Tobacco Registration and Product Listing Module (TRLM) Step-by-Step Instructions

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1. Enter New Tobacco Registration and Product Listing

1.1 New Registration and Product Listing

1.1.1 Log into TRLM

After logging into the FDA Unified Registration and Listing System (FURLS), users can select "**Tobacco Registration and Listing system**" from the list of systems available on the FURLS Home Page (see Figure 1).

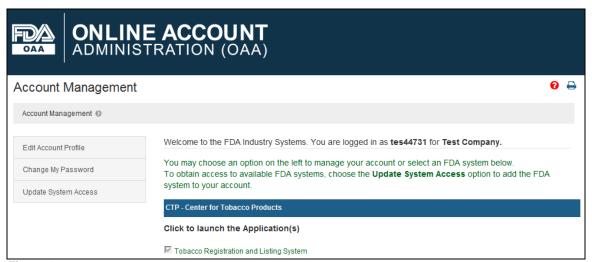


Figure 1

Once users have selected "**Tobacco Registration and Listing System**," users will navigate to the TRLM Main Menu page as shown in Figure 2 below.

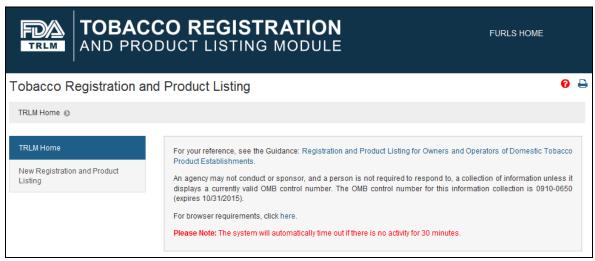


Figure 2

To begin the initial registration process, users can select "New Registration and Product Listing."

Once users have selected the "**New Registration and Product Listing**" option from the main menu, users will navigate to Section I – Identification as shown in Figure 4 below.

1.1.2 Navigation



Figure 3

The 'FURLS HOME' and "TRLM HOME' links, located at the top-right corner of the page, will take users to the respective main menus. (FURLS HOME-Refer to Figure 1 above; TRLM HOME-Refer Figure 3 above) To log out of the system, users may select 'FURLS HOME' and click on 'Logout' at the top right corner of the page.

1.2 Section I - Identification

When preparing a new registration, users will need to identify the submitter type from the following options:

- Owner Registering Alone
- Owner Registering on Behalf of Operator
- Owner who is also Operator of all Establishments
- Operator Registering Alone
- Operator Registering on Behalf of Owner

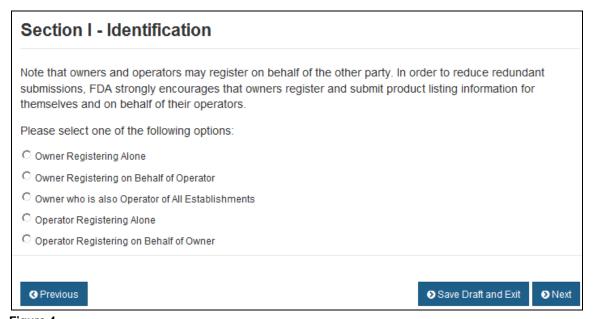


Figure 4

- If users select "Owner Registering Alone," the system will not display Section IIIA –
 Registration (Operator Information) and Section IIIB Registration (Operator Business
 Structure) pages. For any other submitter type users select, Sections IIIA and IIIB will
 be displayed.
- If users select "Operator Registering Alone," the system will not display Section IIA –
 Registration (Owner Information) and Section IIB Registration (Owner Business
 Structure) pages. For any other submitter type users select, Sections IIIA and IIIB will

be displayed.

- If users select "Owner Who is also Operator of All Establishments," Section IIIA –
 Registration (Operator Information) will be automatically populated with the Owner's
 information from Section IIA. The data automatically populated in Section IIIA is readonly and cannot be edited.
- If users select "Owner who is also Operator of All Establishments," Section IIIB –
 Registration (Operator Business Structure) will be automatically populated with the
 Owner's business structure information from Section IIB. The data automatically
 populated in Section IIIB is read-only and cannot be edited.

1.3 Section IIA - Registration (Owner Information)

This page will display the "Owner Information" and "Owner Point of Contact" sections.

▲ Section IIA - Registration (Owner Information	,u,		
	Autofill from Account Information		
Owner Information	Owner Point of Contact (Optional)		
Owner information	Owner Form of Contact (Optional)		
Owner Name (Name of the Corporation / Partnership or Individual Owner)	Title		
Test Company	Mr.		
The term "owner" means a person, as defined in section	First / Given Name		
201(e) of the Act (21 U.S.C. 321 (e)), who has an ownership interest in an establishment.	Help		
Address Line 1	Middle Name		
11820 Help Guide Dr			
Address Line 2 (Optional)	Last Name		
	Guide		
Country	Position Title		
UNITED STATES	Staff		
ZIP or Postal Code	Email Address		
20852	help.guide@test.com		
Please enter "NONE", if Zip codes are not used in			
selected Country/Area.	Telephone (Include Country Code if applicable)		
City	001 301 5555555		
Rockville	Country Area Phone Number Extension		
State, Province or Territory	Fax		
Maryland	001		
maryiand	Country Area Fax Number		
Owner Headquarters D&B DUNS Number (Optional)			

Figure 5

On this page users will provide details for the Owner and the Owner Point of Contact. Users can enter the information or select the "**Autofill from Account Information**" option, which will fill in relevant information from the user's FURLS Account Information.

1.4 Section IIB - Registration (Owner Business Structure)

This page will display the Owner's Business Structure Information.

Section IIB - Registration	n (Owner Business Structure)
	re and provide indicated information.
○ Sole Proprietorship ○ Partnership ○ Corporation If the owner does business by any other name, please list all such name.	

Figure 6

On this page users will select the Owner business structure from the following options and provide the indicated information:

- Sole Proprietorship
- Partnership
- Corporation

1.4.1 Section IIB – Sole Proprietorship

▲ Section IIB - Registration (Owner Business Structure)
Select the type of business structure a Sole Proprietorship Partners Enter Owner Name	_
Help Guide	
If the owner does business by any o	other name, please list all such names. • Add Another Business Name

Figure 7

If users select "**Sole Proprietorship**", they will need to enter the Owner name. If the Owner does business by any other name, users can list all such names by clicking the "**Add another Business Name**" button.

1.4.2 Section IIB - Partnership

▲ Section IIB - Registration (Owner Business Structure)
Select the type of business structure and provide indicated information.
○ Sole Proprietorship
Enter Name of the Partner 1
Jane Doe
Enter Name of the Partner 2
Add Another Partner
If the owner does business by any other name, please list all such names.
Add Another Business Name

Figure 8

If users selected "**Partnership**", they will be required to enter at least two partner names. If there are more than two partners, users can list all partners by clicking the "**Add Another Partner**" button. If the Owner does business by any other name, users can list all such names by clicking the "**Add another Business Name**" button.

1.4.3 Section IIB – Corporation

Section IIB - Registration	(Owner Business Structure)			
elect the type of business structure	and provide indicated information.			
Sole Proprietorship © Partner	rship © Corporation			
Enter the name of each corporate	officer or director			
Enter Name of the Individual Jane Doe				
				Add Corporate Officer or Director
			Identify State of incorporation	
District of Columbia	•			
Please describe further. (If applicable, give name of country if				
incorporation made outside U.S.).				
If the owner does business by any	other name, please list all such names.			
	Add Another Business Name			

Figure 9

If users select "Corporation", they will need to enter the name of each corporate officer or director in the field labeled "Enter Name of the Individual." If there are additional corporate officers or directors, users can enter multiple names by clicking the "Add Corporate Officer or Director" button as necessary. If the Owner does business by any other name, users can list all such names by clicking the "Add another Business Name" button.

Once users have completed this section they can select the "**Next**" button to navigate to Section IIIA. (See Figure 12 below.)

1.4.4 Address Validation

The system will perform an address validation. If the address entered is found to be valid, no action is taken. If there are minor differences to the provided address the system will display the validated address (as shown in Figure 10). If the address entered cannot be verified, the system will display a warning message (as shown in Figure 11).

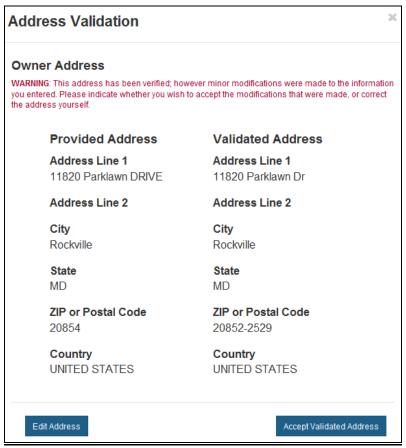


Figure 10

The system will display the validated address if there are minor differences to the offered address. Users can make changes to the address entered by selecting the "Edit Address" button. Otherwise, users can select the "Accept Provided Address" button to proceed to Section IIIA.

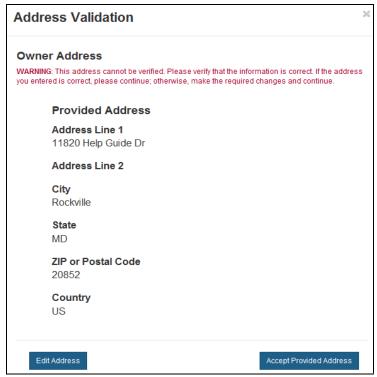


Figure 11

The system will display a warning message when the address entered cannot be verified. Users can make changes to the address entered by selecting the "Edit Address" button. Otherwise, users can select the "Accept Provided Address" button to proceed to Section IIIA.

1.5 Section IIIA - Registration (Operator Information)

This page will display the Operator information and the Operator Point of Contact sections. This page will not be displayed if users select the submitter type "Owner registering alone" in Section I: Identification.

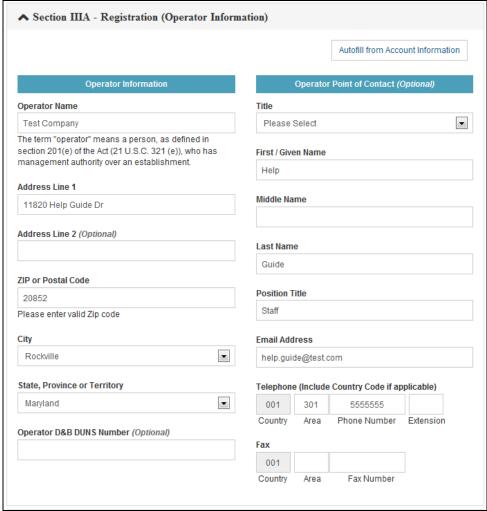


Figure 12

On this page users will provide details for the Operator and the Operator Point of Contact. Users can enter the information or select the "Autofill from Account Information" option, which will fill in the relevant information from the users' FURLS Account Information.

1.6 Section IIIB - Registration (Operator Business Structure)

This page will display the "**Operator Business Structure Information**". This page will not be displayed if users select the submitter type "**Owner Registering Alone**" in Section I: Identification.

1.6.1 Section IIIB – Registration (Operator Business Structure)

▲ Section IIIB - Registration (Operator Business Structure)		
Select the type of business structure and provide indicated information. C Sole Proprietorship C Partnership C Corporation		
If the operator does business by any other name, please list all such names.		
Add Another Business Name		

Figure 13

On this page users will need to select the "**Operator Business Structure**" from the following options and provide the indicated information:

- Sole Proprietorship
- Partnership
- Corporation

1.6.2 Section IIIB – Sole Proprietorship

elect the type of business structure and provide indicated information. Sole Proprietorship C Partnership C Corporation
Sole Proprietorship C Partnership C Corporation
Enter Operator Name
John Doe

Figure 14

If users select "**Sole Proprietorship**", they will need to enter the Operator's name. If the Operator does business by any other name, users can list all such names by selecting the "**Add another Business Name**" button.

1.6.3 Section IIIB – Partnership

▲ Section IIIB - Registration (Operator Business Structure)	
colors the type of husiness structure and provide indicated information	
elect the type of business structure and provide indicated information.	
Sole Proprietorship © Partnership C Corporation	
Enter Name of the Partner 1	
John Doe	
Jane Doe	
Add Another Partner	
If the operator does business by any other name, please list all such names.	
Add Another Business Name	

Figure 15

If users select "Partnership" they will be required to enter at least two partner names. If there are more than two Partners, users can list all the partners by clicking the "Add Another Partner" button. If the Operator does business by any other name, users can list all such names by clicking the "Add another Business Name" button.

1.6.4 Section IIIB – Corporation

Add Corporate Officer or Director Intify State of incorporation Invariant arrivable, give name of country if		
ole Proprietorship © Partnership © Corporation er the name of each corporate officer or director. er Name of the Individual ohn Doe Add Corporate Officer or Director ntify State of incorporation laryland asse describe further. (If applicable, give name of country if orporation made outside U.S.).	Section IIIB - Registration (Op	erator Business Structure)
ole Proprietorship © Partnership © Corporation er the name of each corporate officer or director. er Name of the Individual ohn Doe Add Corporate Officer or Director ntify State of incorporation laryland asse describe further. (If applicable, give name of country if orporation made outside U.S.).		
er the name of each corporate officer or director. er Name of the Individual ohn Doe Add Corporate Officer or Director ntify State of incorporation laryland ase describe further. (If applicable, give name of country if orporation made outside U.S.).	ect the type of business structure and p	rovide indicated information.
er Name of the Individual Thin Doe Add Corporate Officer or Director Intify State of incorporation Iaryland ase describe further. (If applicable, give name of country if orporation made outside U.S.).	Sole Proprietorship © Partnership	© Corporation
Add Corporate Officer or Director Intify State of incorporation Iaryland ase describe further. (If applicable, give name of country if orporation made outside U.S.).	inter the name of each corporate officer	or director.
Add Corporate Officer or Director Intify State of incorporation Interpolation Intify State of incorporation Intify State	nter Name of the Individual	
aryland ase describe further. (If applicable, give name of country if orporation made outside U.S.).	John Doe	
aryland ase describe further. (If applicable, give name of country if orporation made outside U.S.).		
ase describe further. (If applicable, give name of country if orporation made outside U.S.).	•	Add Corporate Officer or Director
ase describe further. (If applicable, give name of country if orporation made outside U.S.).	dentify State of incorporation	
orporation made outside U.S.).	Maryland	▼
e operator does business by any other name, please list all such names	Please describe further. (If applicable, ncorporation made outside U.S.).	give name of country if
e operator does business by any other name, please list all such names		
e operator does business by any other name, please list all such names		
e operator does business by any other name, please list all such names		
	the operator does business by any oth	er name, please list all such names

Figure 16

If users select "Corporation", they will need to enter the name of each corporate officer or director in the field labeled "Enter Name of the Individual". If there are additional corporate officers or directors, users can enter multiple names by clicking the "Add Corporate Officer or Director" button as necessary. If the Operator does business by any other name, users can list all such names by clicking the "Add another Business Name" button.

Once users have completed this section they can click on the "**Next**" button to submit the "**Operator Information & Operator Business Structure**", which appears above Section IIIA&B. (See Figure 17 below.)

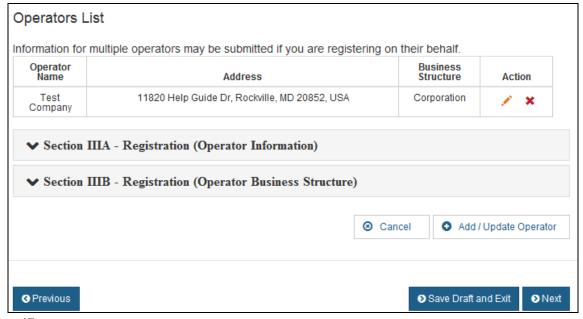


Figure 17

Please note that this will not be displayed when the submitter type in Section I: Identification is selected as "Owner who is also Operator of all Establishments." The "Operator Name", "Address", and "Business Structure" of each Operator entered in the registration shall be

displayed. Users can edit a specific Operator's information be edited by clicking the icon in the action column. Users can delete a specific Operator by clicking the icon in the action column. Users can add multiple Operators to the registration by clicking the "Add/Update Operator" button.

Once users have completed editing the Operator's information or adding Operators to the registration they can click on the "**Next**" button to navigate to Section IV: Establishment Information. See Figure 20 below.

1.6.5 Address Validation

The system will perform an address validation. If the address entered is found to be valid, no action is taken. If there are minor differences to the provided address, the system will display the validated address as shown in Figure 18. If the address entered cannot be verified the system will display a warning message, (as shown in Figure 19).

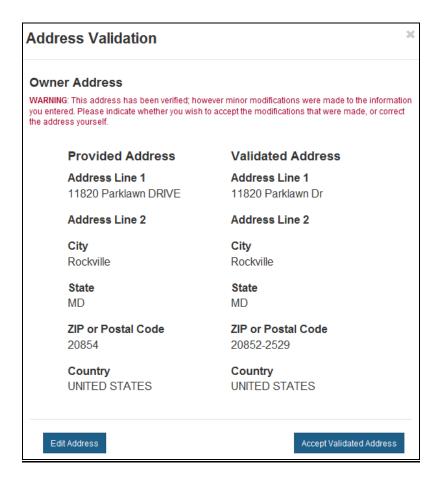


Figure 18

The system will display the validated address if there are minor differences to the requestor address. Users can make changes to the address entered by selecting the "Edit Address" option. Otherwise, users can select the "Accept Provided Address" button to proceed to Section IIIA.

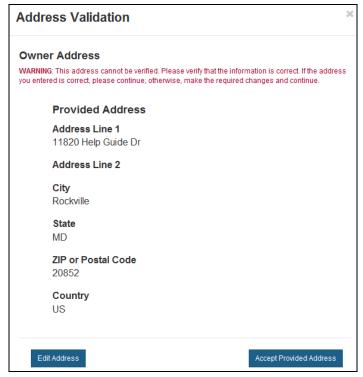


Figure 19

The system will display a warning message when the address entered cannot be verified. Users can make changes to the address entered by selecting the "Edit Address" option. Otherwise, users can select the "Accept Provided Address" button to proceed to Section IIIA.

1.7 Section IV - Establishment Information

This page will display the "Establishment Information" and "Establishment Point of Contact" information.

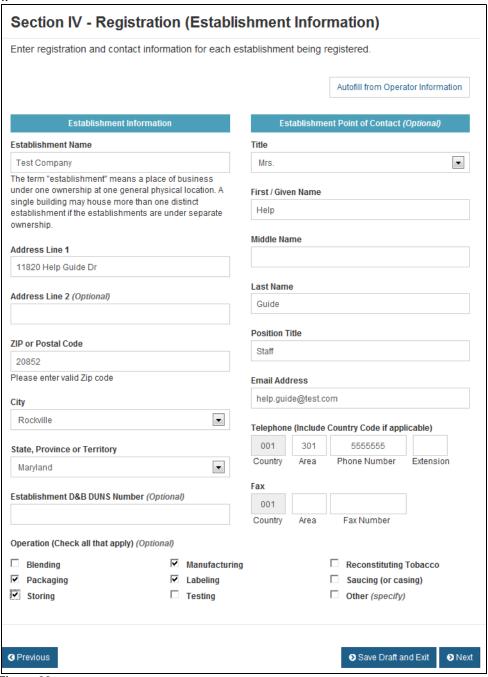


Figure 20

In Section IV users enter information about establishment(s). Users can enter the "Establishment" and "Point of Contact" information themselves or select the "Autofill from Operator Information" option will fill in the

relevant information from Section IIIA and Section IIIB. The prefilled information may be edited as required.

The "Autofill from Operator Information" button will not be displayed when the registration has more than one Operator. When the registration has more than one Operator, users will need to select at least one Operator from the "Select Operator(s) for this establishment" multiple-select list box as displayed in Figure 21 below. If required, users may select multiple Operators to be associated with the establishment.



Figure 21

1.7.1 Address Validation

The system will perform an address validation. If the address entered is found to be valid, no action is taken. If there are minor differences to the provided address, the system will display the validated address (as shown in Figure 22). If the address entered cannot be verified, the system will display a warning message (as shown in Figure 23).

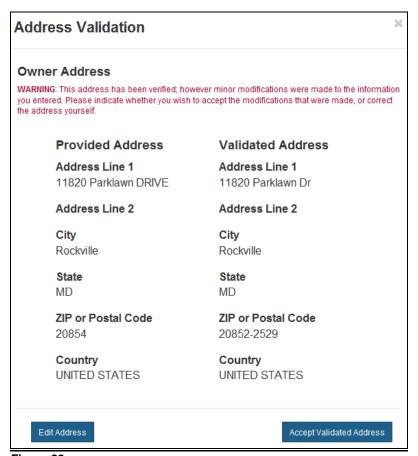


Figure 22

The system will display the validated address if there are minor differences to the requestor address. Users can make changes to the address entered by selecting the "Edit Address" option. Otherwise, users can select the "Accept Provided Address" button to proceed to Section IIIA.

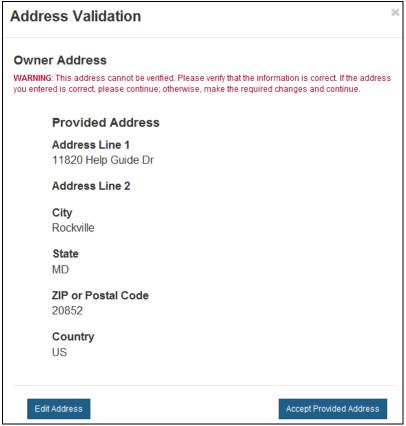


Figure 23

The system will display a warning message when the address entered cannot be verified. Users can make changes to the address entered by selecting the "**Edit Address**" option. Otherwise, users can select the "**Accept Provided Address**" button to proceed to Section IIIA.

1.8 Section V - Product Listing

In Section V users enter information about products. Every active establishment must have at least one "**Product Listing**". For each listing users can enter required product information; this includes advertising, labeling, and consumer information materials.

Users can enter Product Listing information in two ways:

- 1. "Upload Product Listing Information with an Excel File"
- 2. "Enter Product Listing Information Manually"

ection v - Registra	ntion (Product Listing)	
ablishment Name: Test Co nually enter product infor	ompany rmation or upload product listing(s	s) from a file.
Option I: Upload From F	ile	
You may upload product listin Maximum allowed file size 50	ngs from an Excel spreadsheet. Downl 0 MB.)	load the Product Listing Template.
Select the file to upload for produc	ct listing(s) † Upload	
Option II: Manually Enter	r Product Information	
1. Product Name (i.e., brand/sub- e.g., Acme Blue 100's or Acme I	brand or other commercial name used in co Reconstituted Tobacco #202)	ommercial distribution -
2. Product Identification Number ((Must be provided if needed to uniquely iden	tify the product)
3. Type of Product Identification No	umber (Select One)	© UPC Number
Intended Use of Product (Select Consumer Use	ct One)	
5. Consumer Use Product Catego	-	
□ Cigarettes	Roll-Your-Own Tobacco	Roll-Your-Own Paper
Chewing Tobacco	Roll-Your-Own Filters	□ Snus
□ Dissolvables	□ Dry Snuff	Other (Specify)
☐ Accessory Filters	☐ Moist Snuff	
3. Further Manufacturing Use Prod	duct Category (Check applicable)	
□ Tobacco	☐ Filters	Additive
Paper	Pouch for Portioned Tobacco	Other (Specify)
7. Flavor (Check applicable)		
☐ Menthol	□ None	☐ Other (Specify)

Figure 24

1.8.1 Option 1: Upload From File

Users may upload Product Listings from an Excel spreadsheet. The spreadsheet can be downloaded by clicking on the "**Product Listing Template**." A maximum of allowed file size is 50 MB.

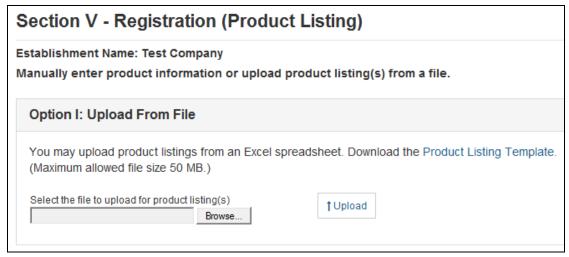


Figure 25

To complete the template to be uploaded, users can enter information for the first" beginning in row 2 of the template. Users can continue adding products in subsequent rows. Do not delete row 1 or add/delete a column in the template.

The template consists of eight columns. Each column contains its own help to guide users through the process.

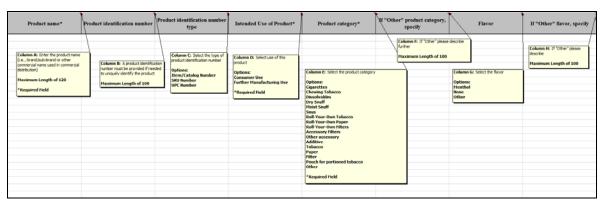


Figure 26

- Column A (required) "Product Name"
 - Users can enter up to 120 characters.
- Column B (optional) "Product Identification Number"
 - Users can enter up to 100 characters.
- Column C (required if column B completed) "Product Identification Number Type"
 - If users entered a value in Column B, users must select a value from the pick list.
 Otherwise, users should leave column C blank.
- Column D (required) "Use of this Product"
 - Users must select a value from the pick list.

- Column E (required) "Product Category"
 - Users must select a value from the pick list.
- Column F (required if "Other" selected in Column E) If "Other..." Product Category
 - If users selected "Other" in Column E, they must enter a value in Column F.
 Otherwise, users should leave Column F blank.
- Column G (optional) Flavor
 - Users can select a value from the pick list.
- Column H (required if "Other..." selected in Column G)
 - If "Other" is selected in Column G, then users must enter a value in Column H.
 Otherwise, users should leave Column H blank.

If the template upload is successful, the system will display a list of the products that were uploaded. Users must complete each Product Listing by either uploading all labeling for the product or by indicating that the product has no labeling. Users may also upload all consumer information and a representative sample of advertising for the product. Users will not be able to submit a registration until all Product Listings are complete.

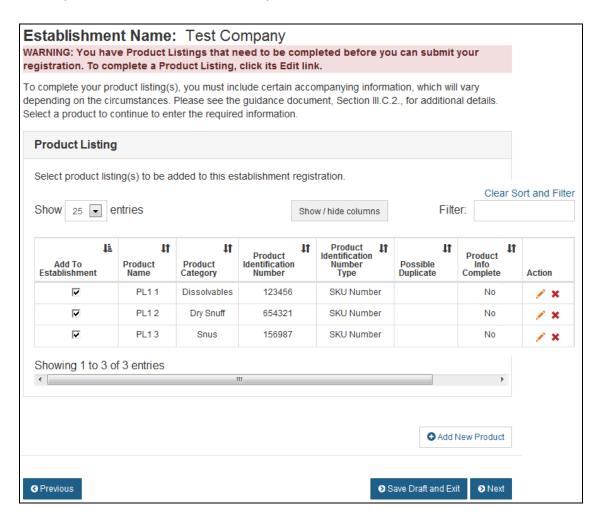


Figure 27

To complete the Product Listing(s), users must include certain accompanying information; this information will vary depending on circumstances. Section III.C.2. of the Guidance document can be used as reference for additional details.

Users can select a product to continue to enter the required information.

Users can select the /* icon in the right column to complete or edit a Product Listing.

When users select a Product Listing to complete, the system will display the Product Listing Review page.

Users can click the "**Edit**" button to complete any section. Users must edit the "**Labeling**" section to upload all labeling or, indicate the product has no labeling before they may continue the registration.

Users can click "Continue to Product Listings" to return to the list of uploaded Product Listings.

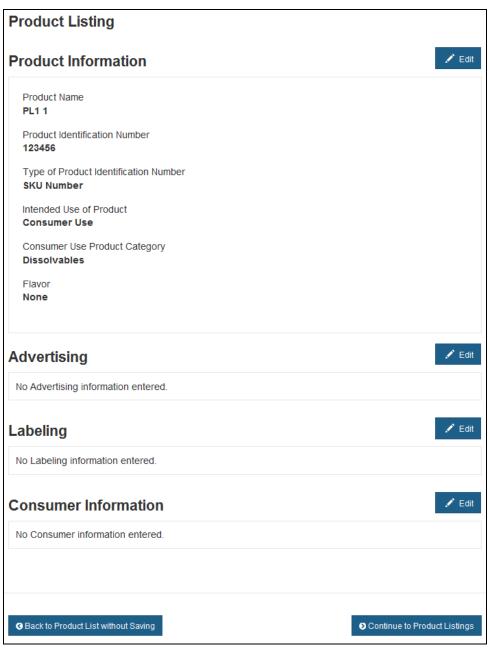


Figure 28

1.8.2 Option 2: Enter Manually

Option II: Manually Enter	Product Information	
1. Product Name (i.e., brand/sub-b e.g., Acme Blue 100's or Acme F	rand or other commercial name used in c leconstituted Tobacco #202)	commercial distribution -
PL1 4		
2. Product Identification Number (N	lust be provided if needed to uniquely ider	ntify the product)
9866547		
3. Type of Product Identification Nu	mber (Select One)	
C Item/Catalog Number	© SKU Number	C UPC Number
4. Intended Use of Product (Select	One)	
© Consumer Use	C Further Manufacturing Use	
5. Consumer Use Product Catego	y (Check applicable)	
☐ Cigarettes	Roll-Your-Own Tobacco	Roll-Your-Own Paper
Chewing Tobacco	Roll-Your-Own Filters	□ Snus
Dissolvables	☐ Dry Snuff	☐ Other (Specify)
☐ Accessory Filters	✓ Moist Snuff	
6. Further Manufacturing Use Prod	uct Category (Check applicable)	
N/A		
7. Flavor (Check applicable)		
Menthol	▽ None	Other (Specify)
3 Previous		Save Draft and Exit

Figure 29

• Product Name (required)

 Brand/sub-brand or other commercial name used in commercial distribution (e.g., Acme Blue 100s). Users can enter up to 120 characters for Product Name.

• Product Identification Number (optional)

Users can enter up to 100 characters. Users must enter a "Product Identification Number" if needed to uniquely identify the product. If users enter a Product Identification Number users also must enter "Type of Product Identification Number."

- Type of Product Identification Number (required if Product Identification Number was entered)
 - If users entered a Product Identification Number, users must select a "Type of Product Identification Number."
- Intended Use of Product (required)
 - Users must select either "Consumer Use" or "Further Manufacturing Use."
- Consumer Use Product Category (required if Consumer Use was selected for Intended Use of Product)
 - Users must select one or more "Product Categories". If the appropriate Product Category is not listed, users must select "Other" and enter its category in the text field.
- Further Manufacturing Use Product Category (required if Further Manufacturing was selected for Intended Use of Product)
 - Users must select one or more uses. If the appropriate Product Category is not listed, users must select "Other," and enter its category in the text field.
- Flavor (optional)
 - Users can select one or more "Flavors." If the product's flavor is not listed, users can select "Other" and enter a flavor in the text field.

When users choose "**Next**" to continue from the Product Information page, the system will display the Advertising, Labeling and Consumer Information page; (see Figure 30.)

1.8.3 Add Advertising

A representative sampling of adve III.C.2., for additional details.	rtising may be required. Please s	see the guidance document, Section	1	
	MB. Please Note: If the upload tir	me exceeds 30 minutes, the system	will	
For each advertisement, we reque	st that you provide the following	optional information:		
Type of Advertising Material (e.g	Magazine)			
Internal Identification Number, as				
Date Advertisement was First Dis				
Product Name: PL1 4				
Advertising	Labeling	Consumer Information		
dvertising				
ype of Advertising Material (e.g., magaz	ine ad)			
Magazine Ad				
DA interprets 'a representative sampling excluding labeling) that reflects the full rar roduct. For example, if more than one ma ontent is essentially identical, only one no	nge of promotional statements made agazine advertisement is used but the	for the tobacco		
itle				
Help Guide Advertising				
nique ID or Internal ID Number 5555				
5555				
ate First Disseminated (mm/dd/yyyy)				
05/01/2015				
pload File (Maximum size for each file is	s 50 MB)			
		Upload		
Product has no Advertising he file was uploaded successfully.				
File Name	File Size (MB)	Action		
Testxlsx 0.013		×		
Go to Labeling	⊗ Cancel	 Add / Update 		

Figure 30

A representative sampling of advertising for the product may be required. Users should refer to the guidance document, Section III.C.2, for additional details.

Users can enter information about the product's advertising. Users can <u>upload</u> advertising or indicate that the product has no advertising by checking the "**Product has no Advertising**" box. If users upload advertising file(s) for the product, they also have the option to enter details about the product's advertising, including:

Type of Advertising (optional)

o Users can enter up to 120 characters.

Title (optional)

Users can enter up to 120 characters.

• Unique ID or Internal ID Number (optional)

Users can enter up to 40 characters.

Date First Disseminated (optional)

Users can select a date from the calendar icon or enter a date. This date is the time of initial dissemination of the labeling, consumer information, or at the time of initial publication of the advertisement for the product.

When the user has finished uploading the product's advertising and selecting "Add / Update" the system will list a table of the Product information.

To edit advertising, users can click on the icon to display the previously entered Advertising Information. To delete advertising, users can click on the icon.

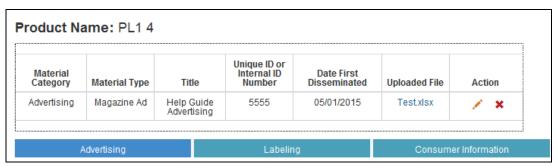


Figure 31

From the Advertising information, users can add Label information by clicking on the "**Labeling**" button.

1.8.4 Add Labeling

Material Category	Material Type	Title	Unique ID or Internal ID Number	Date Firs Disseminat	t ted Uploaded File	Action		
Advertising	Magazine Ad	Help Guide Advertising	5555	05/01/201	5 Test.xlsx	/ ×		
,	Advertising		Labelir	19	Consumer Information			
Labeling								
_	ct Code(s) (UPC)							
45678								
	Material (e.g., pa	ackage label)						
Package Label								
other written, pri	ig' based on secti nted or graphic m accompanying si	atter (1) upon any						
Title								
Help Guide La	bel							
	ernal ID Number							
654321								
Date First Disse	minated (mm/dd/	уууу)						
05/01/2015								
Upload File (Max	dimum size for ea	nch file is 50 MB)	Brows	t tUp	load			
			Diow					
Product has	_							
The file was u	ploaded succes	ssfully.						
File Name			File Size (MB)		Action			
Test.xlsx			0.013		×	×		
						j		
Back to Adver	tising	Go to Consumer	€	Cancel	• Add / Update			

Figure 32

Users can enter information about the product's labeling on the Labeling Information page. Users must <u>upload</u> at least one labeling file or indicate that the product has no labeling by checking the "**Product Has No Labeling**" box for each product. If users upload labeling file(s) for the product, they also have the option to enter details about the product's labeling, including:

Product UPC code(s) (optional)

Users can enter one or more UPC codes separated by commas.

Type of Labeling Material (optional)

Users can enter up to 120 characters.

• Title (optional)

o Users can enter up to 120 characters.

• Unique ID or Internal ID Number (optional)

Users can enter up to 40 characters.

Date First Disseminated (optional)

 Users can select a date from the Calendar icon or enter a date. This date is the time of initial dissemination of the labeling, consumer information, or at the time of initial publication of the advertisement for the product.

When the user has finished uploading the product's labeling and selecting "Add / Update" the system will list a table of the Product information.

To edit labeling, users can click on the sicon to display the previously entered Labeling Information. To delete labeling, users can click on the sicon.

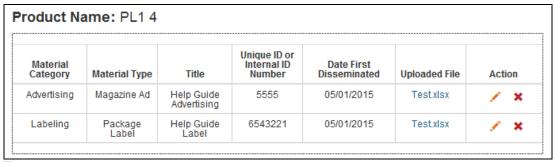


Figure 33

From the Label information, the user can add Consumer information by clicking on the "Go to Consumer Information" button.

1.8.5 Add Consumer Information

Material Category	Material Type	Title	Unique ID or Internal ID Number	Date First Disseminated	Uploaded File	Action	
Advertising	Magazine Ad	Help Guide Advertising	5555	05/01/2015	Test.xlsx	<i>A</i> *	×
Labeling	Package Label	Help Guide Label	6543221	05/01/2015	Test.xlsx		×
,	Advertising		Labelin	ıg	Consumer Information		
onsumer	Information						
pe of Consum	ner Material (e.g.,	consumer broc	hure)				
Consumer Bro	chure						
stributors, or re	etailers, where su	ch information is	not available to o	consumers.			
lelp Guide Bro	ochure						
2345	ernal ID Number						
2040							
	minated (mm/dd/		<u></u>				
5/01/2015							
load File (Max	ximum size for ea	ch file is 50 MB)		Autorod			
			Brows	t Upload			
Product has	no Consumer Info	ormation					
e file was u	ploaded succes	sfully.					
	File Name		File Size /ME	n	Action		
File Name			File Size (MB) 0.013				
Test.xlsx			0.013		×		
Dook to Lobel	ing		8	Cancel 💿	Add / Update		
Back to Label							
Back to Laber							

Figure 34

Consumer information may be required. Users should refer to the Section III.C.2 Guidance document for additional details.

Users can enter information about the product's consumer on the Consumer Information page. Users can <u>upload</u> consumer information or indicate that the product has no consumer information by checking the "**Product has no Consumer Information**" box. If users upload consumer information file(s) for the product, they also have the option to enter details about the product's consumer information, including:

Type of Consumer Information (optional)

Users can enter up to 120 characters.

• Title (optional)

Users can enter up to 120 characters.

• Unique ID or Internal ID Number (optional)

Users can enter up to 40 characters.

• Date First Disseminated (optional)

 Users can select a date from the calendar icon or enter a date. This date is the time of initial dissemination of the labeling, consumer information, or at the time of initial publication of the advertisement for the product.

When the user has finished uploading the product's Consumer Information and selecting "Add / Update" the system will list a table of the Product information.

To edit labeling, users can click on the sicon to display the previously entered Labeling Information. To delete labeling, users can click on the sicon.

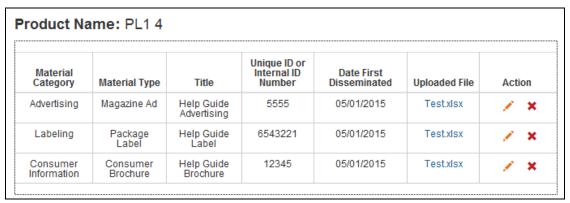


Figure 35

When users select the "**Next**" button the system will display the Product Listing page. (See Figure 36.)

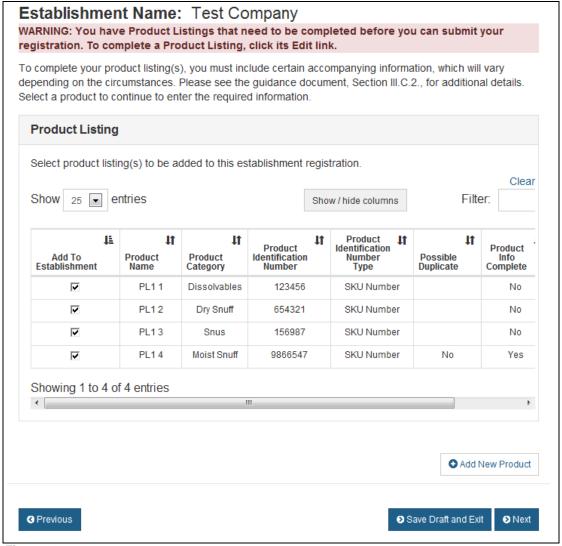


Figure 36

The Product Listing page is a summary list of the products that were added to the registration. From the Product Listing page users can select a product to edit or delete or users also can choose to add another product.

If users select a Product Listing to edit, the system first will display the Product Listing Information page. Users can edit the Product Listing Information or choose to "Next."

1.9 Registration Review Page

Once users have completed entering the Product Listing information they will be navigated to the Establishment Information page. (See Figure 37.)

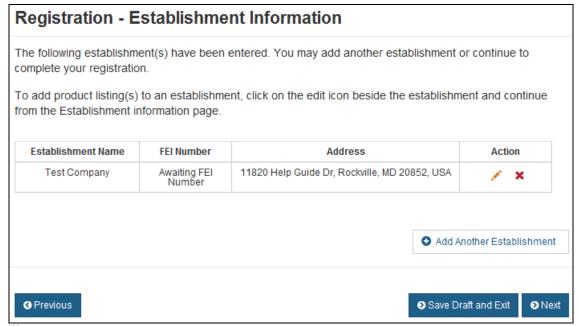


Figure 37

This page will display the name and address of the establishment(s) users have entered. Users can edit a specific establishment's information by clicking the icon in the last column. Users can delete an establishment by clicking the icon in the last column.

Users can add another establishment by selecting the "Add another Establishment" button or, continue to complete the registration by selecting the "Next" button. If users choose to "Add another Establishment." They will be navigated to the Section IV - REGISTRATION (Establishment Information) page, where users can enter information for the new establishment.

After Section IV has been completed for the second establishment, the system will display a list of products that were added to the registration.

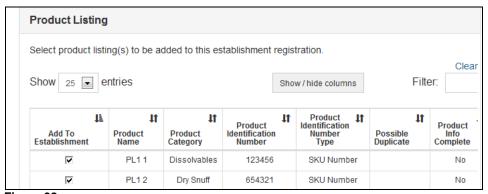


Figure 38

Users can select products from the list to associate with the second establishment. They also can choose to add a new product. Users must select at least one product from the list or add a Product Listing. Product Listings added while registering the second establishment will be associated with the second establishment. Users can associate added products for the second establishment with other establishments by choosing to edit an establishment from the Establishment Information page.

Once users have completed editing the establishment's information or adding establishments to the registration, they should click on the "**Next**" button to navigate to the Registration Review page. (See Figure 39 below.)

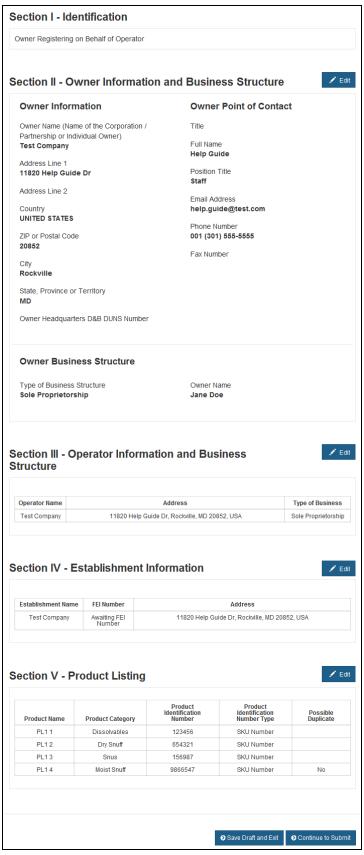


Figure 39

After reviewing the registration, users can click on the "Continue to Submit" button to navigate to Section VI: Confirmation Statement. (See Figure 40 below.)

1.10 Section VI – Confirmation Statement

This page will display the Confirmation Statement.

NOTE: Users must agree to the Confirmation Statement before submitting.

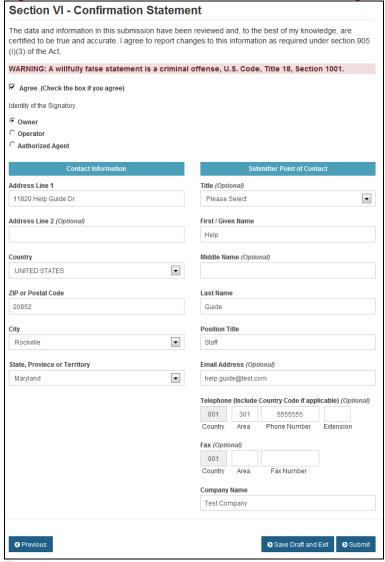


Figure 40

On the Confirmation Statement page users are required to select the Identity of the Signatory. The options are: "Owner", "Operator", or "Authorized Agent."

- If users select "Owner," the relevant contact information fields will be pre-filled with Contact Information for the Owner from Section IIA and can be edited.
- If users select "Operator," the relevant contact information fields will be pre-filled with contact information for the Operator from Section IIIA and can be edited. When the registration has more than one Operator, users can select the Operator from the dropdown list.
- If users select "Authorized Agent," they must enter the authorized agent's contact information.

Upon completion of this section, the registration is ready for submission. Click on the "**Submit**" button. The system will display a message that users' registration and Product Listing information has successfully been submitted, (as shown in Figure 41 below). In order to receive

notifications, users should configure their email's Spam or Junk folders to allow messages from CTPRegistrationandListing@fda.hhs.gov.

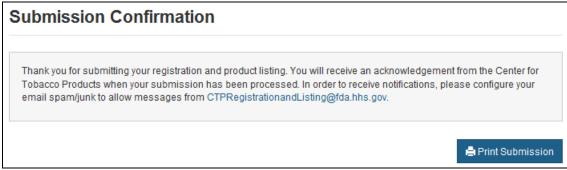


Figure 41

Users may print the submission by selecting the "**Print Submission**" button, or return to the TRLM Main Menu by selecting the "**TRLM Home**" hyperlink on the screen. If users select "**Print Submission**" a new browser window will open which will allow users to print the registration information. When finished, users can close the browser window in order to return to the TRLM application.

1.11 Save Draft and Exit

During the registration process, users may select the "Save Draft and Exit" option to save partially completed information users have entered up to this point. The system will display a message showing the last date to submit a registration before the draft is deleted.

U.S. Department of Health and Human Ser TOBACC TRLM AND PROD	O REGISTRATION OUCT LISTING MODULE	FURLS HOME TRLM HOME		
Tobacco Registration and	Product Listing	∂ -		
TRLM Home New Registration and Produ	uct Listing			
TRLM Home	Section IV - Registration (Estab	olishment Information)		
New Registration and Product Listing	Enter registration and contact information for each e	establishment being registered.		
	Establishment Information	Establishment Point of Contact (Optional)		
	Establishment Name	Title		
	Establishment One	Please Select		
	The term "establishment" means a place of business under one ownership at one general physical location. A single	First / Given Name		
	building may house more than one distinct establishment if the establishments are under separate ownership.	Jamie		
	Address Line 1	Middle Name		
	7400 Fullerton Road			
	Address Line 2 (Optional)	Last Name Jones		
	ZIP or Postal Code	Position Title		
	22153	Vice President		
	Please enter valid Zip code			
	City	Email Address		
	Springfield	dennis.chambers@fda.hhs.gov		
	State, Province or Territory	Telephone (Include Country Code if applicable)		
	Virginia	Country Area Phone Number Extension		
	Establishment D&B DUNS Number (Optional)	Fax		
		001		
		Country Area Fax Number		
	Operation (Check all that apply) (Optional)			
	✓ Blending	g Reconstituting Tobacco		
	▼ Packaging	Saucing (or casing)		
	Storing Testing	Other (specify)		
	3 Previous	Save Draft and Exit Next		

Figure 42

1.12 Draft Confirmation

The user has the option from the Draft Confirmation to print the draft by clicking the "**Print Draft**" button to print. See Figure 43.

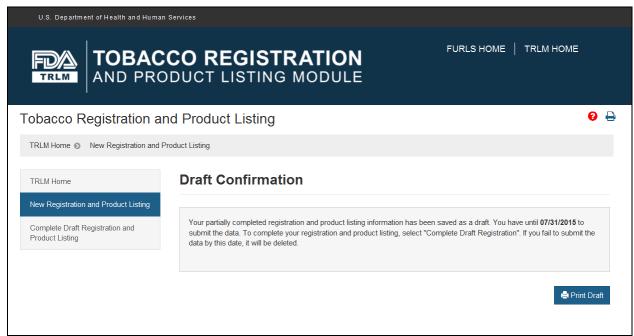


Figure 43

1.13 Print Draft

CENTER FOR TOBACCO PRODUCTS					
Not Submitted			Draft Submitted On:	07/24/2015	
Account Id: new14709			Printed On: 07/24/2015		
SECTION I - IDENT	IFICATION				
Owner who is also (Establishments			
SECTION II - REGI	STRATION (O	wner Informatio	n and Owner Busine	ess Structure)	
Owner Information:					
Owner Name (Name of the Corporation / Partnership or Individual Owner):	New VP Corp		Owner Address:	23 Ranch Ct, North Potomac, MD, 20878-3827, UNITED STATES	
Owner Headquarters D&B DUNS Number:					
Owner Point of Con	tant:				
Title:	aud.		Full Name:	Victor D Smith	
Position Title:	VP		Email Address:	Hsiaofeng.yang@fda.hhs.go v	
Phone Number:	001 (301) 994 23213	-3939 Ext	Fax Number:	001 (240) 995-4841	
Owner Business Str					
Type of Business S	tructure:	Sole Proprieto	rship		
Owner Name:		GREG			
If the owner does b any other name, ple such names:					
OF OTHER DESIGNATION OF THE PERSON OF THE PE	07047104170				
Operator Informatio		perator informa	ition and Operator B	susiness Structure)	
_	New VP Corp		Operator Address:	23 Ranch Ct, North Potomac, MD, 20878-3827, UNITED STATES	
Operator D&B DUNS Number:					
Operator Point of Co	ontact:				
Title:			Full Name:	Victor D Smith	
Position Title:	VP		Email Address:	Hsiaofeng.yang@fda.hhs.go v	
Phone Number:	001 (301) 994 23213	-3939 Ext	Fax Number:	001 (240) 995-4841	
Operator Business					
Type of Business S	tructure:	Sole Proprieto	rship		
Operator Name:		GREG			
If the operator does any other name, ple such names:					

Figure 44

1.14 Complete Draft

Users can continue to complete the Registration and Product Listing by selecting the "Complete Draft Registration and Product Listing" from the left-hand Launchpad. A message will display informing the user the date the draft must be submitted before it will be deleted. Each section of the registration and Product Listing will be displayed with the information that has been previous saved as a draft. The user can edit any section by selecting the "Edit" button for that section. (See Figure 45.)

Once users have edited and complete all of the sections required for the registration and Product Listing they can select the "Continue to Submit" button or "Discard the Draft" If the user selects to discard the draft, the draft changes will be removed from the system.

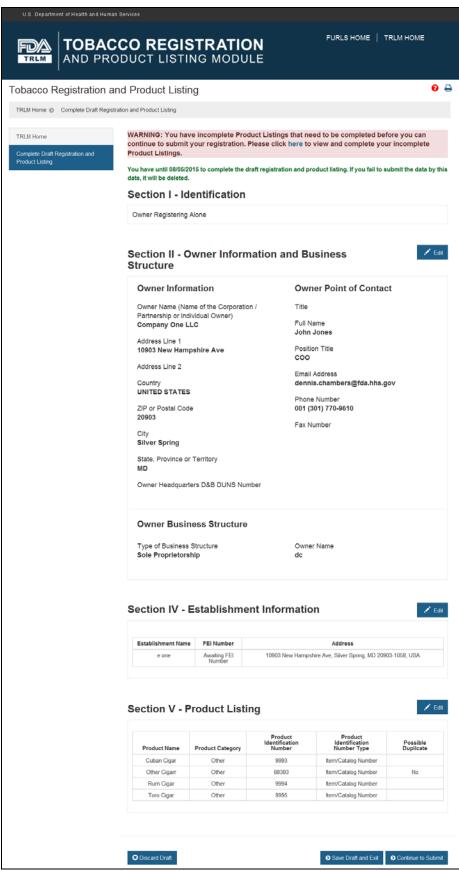


Figure 45

If users click the "Continue to Submit" button they will be navigated to the Confirmation Statement page. See Figure 46 below.

NOTE: Users must agree to the Confirmation Statement before submitting. U.S. Department of Health and Human Services FURLS HOME | TRLM HOME TOBACCO REGISTRATION AND PRODUCT LISTING MODULE **0** 🖶 Tobacco Registration and Product Listing TRLM Home
 Complete Draft Registration and Product Listing Section VI - Confirmation Statement TRI M Home The data and information in this submission have been reviewed and, to the best of my knowledge, are Complete Draft Registration and Product Listing certified to be true and accurate. I agree to report changes to this information as required under section 905 (i)(3) of the Act. WARNING: A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001. lacksquare Agree (Check the box if you agree) Identity of the Signatory Owner O Authorized Agent Submitter Point of Contact Contact Information Address Line 1 Title (Optional) • 11820 Parklawn Dr Please Select Address Line 2 (Optional) First / Given Name Country Middle Name (Optional) • UNITED STATES ZIP or Postal Code **Last Name** 20852 Smith City Position Title • Rockville State, Province or Territory Email Address (Optional) • dennis.chambers@fda.hhs.gov Maryland Telephone (Include Country Code if applicable) (Optional) 001 301 7709610 Country Area Phone Number Extension Fax (Optional) 001 Country Area Fax Number Company Name Test Company One Previous Save Draft and Exit Submit

Figure 46

When the user clicks "**Submit**" they will be taken to the Submission Confirmation page; (see Figure 47) below. The user will have the option of printing the Submission by selecting the "**Print Submission**" where a PDF file of the submitted registration can viewed and printed. (See Figure 48.)

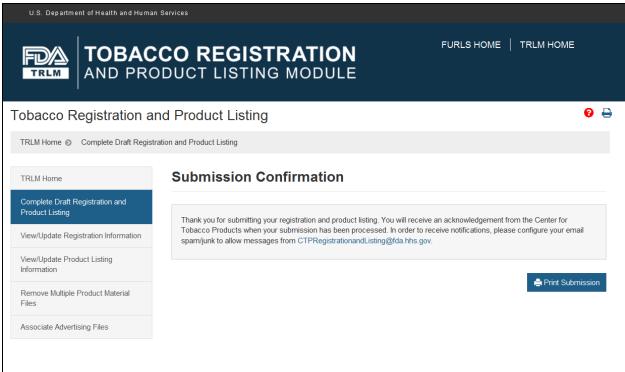


Figure 47

Submitted			Submitted O	Submitted On: 07/20/2015			
Account ld: tes21840				Printed On: 07/20/2015			
Provident la. 1632 1070			Frinted On:	France Oil. 07/20/2013			
SECTION I - ID	ENTIFICATION						
Owner Register							
		(Owner Informa	tion and Owner	Business S	tructure)		
Owner Informat Owner Name		any One	Owner Addre	nee: 110	20 Parklaum	De	
(Name of the Corporation / Partnership or Individual Own	e / or		Owner Addit	Roc	ss: 11820 Parklawn Dr, Rockville, MD, 20852, UNITED STATES		
Owner Headquarters I DUNS Number	D&B						
Owner Point of	Contact:						
Title:			Full Name:	Joe	Smith		
Position Title:	sition Title: Owner		Email Addre	ss: den gov	nnis.chambers@fda.hh		
Phone Number	r; 001 (301) 7	770-9610	Fax Number	:			
	- 01 - 1						
Owner Busines	s Structure:						
Type of Busine	ss Structure:	Sole Proprie	etorship				
Owner Name:		Sole Proprie Joe Smith	etorship				
Owner Name: If the owner do	es Structure: es business by e, please list all		etorship				
Owner Name: If the owner do any other names:	es business by e, please list all						
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I	es business by e, please list all REGISTRATION Name	Joe Smith (Establishment	Information)		Establishm	ent Status	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I	es business by e, please list all REGISTRATION Name	Joe Smith N (Establishment Address 7400 Fullert	Information)	field, VA,	Establishm Active	ent Status	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I	es business by e, please list all REGISTRATION Name	Joe Smith I (Establishment Address 7400 Fullert 22153, UNI 10903 New	Information)	Silver		ent Status	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I Establishment (Establishment	es business by e, please list all REGISTRATION Name One	Joe Smith I (Establishment Address 7400 Fullert 22153, UNI 10903 New Spring, MD,	Information) on Road, Spring TED STATES Hampshire Ave,	Silver	Active	ent Status	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I Establishment Establishment	REGISTRATION Name One Two	Joe Smith I (Establishment Address 7400 Fullert 22153, UNI 10903 New Spring, MD,	on Road, Spring TED STATES Hampshire Ave, 20903, UNITED	Silver STATES	Active Active		
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I Establishment Establishment	REGISTRATION Name One Two	Joe Smith I (Establishment Address 7400 Fullert 22153, UNI 10903 New Spring, MD,	Information) on Road, Spring TED STATES Hampshire Ave,	Silver	Active Active Establ	ishment	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I Establishment Establishment	es business by e, please list all REGISTRATION Name One Two PRODUCT LISTI	Joe Smith N (Establishment Address 7400 Fullert 22153, UNI 10903 New Spring, MD, ING Product Identification	on Road, Spring TED STATES Hampshire Ave, 20903, UNITED	Silver STATES	Active Active Estable Name Estable One;	ishment (s)	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment (Establishment T SECTION V - P Product Name	REGISTRATION Name One Two PRODUCT LISTI Product Category	Joe Smith N (Establishment Address 7400 Fullert 22153, UNI 10903 New Spring, MD, NG Product Identification Number	on Road, Spring TED STATES Hampshire Ave, 20903, UNITED Product Identification Number Type Item/Catalog	Silver STATES Possible Duplicate	Active Active Estable Name Estable One;	ishment (s)	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I Establishment I Establishment I Establishment I Cuban Cigar	REGISTRATION Name One Two PRODUCT LISTI Product Category	Joe Smith I (Establishment Address 7400 Fullert 22153, UNI 10903 New Spring, MD, ING Product Identification Number 12345	on Road, Spring TED STATES Hampshire Ave, 20903, UNITED Product Identification Number Type Item/Catalog	Silver STATES Possible Duplicate	Active Active Estable Name Estable One;	ishment (s)	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I Establishment I Establishment I Establishment I Cuban Cigar	REGISTRATION Name One Two PRODUCT LISTI Product Category Other	Joe Smith I (Establishment Address 7400 Fullert 22153, UNI 10903 New Spring, MD, ING Product Identification Number 12345	on Road, Spring TED STATES Hampshire Ave, 20903, UNITED Product Identification Number Type Item/Catalog	Silver STATES Possible Duplicate	Active Active Estable Name Estable One;	ishment (s)	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I Establishment I Establishment C Establishment C Cuban Cigar CONFIRMATIO	REGISTRATION Name One Two PRODUCT LISTI Product Category Other	Joe Smith I (Establishment Address 7400 Fullert 22153, UNI 10903 New Spring, MD, ING Product Identification Number 12345	on Road, Spring TED STATES Hampshire Ave, 20903, UNITED Product Identification Number Type Item/Catalog	Silver STATES Possible Duplicate	Active Active Estable Name Estable One; Estable	ishment (s)	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I Establishment I Establishment I CUDAN Cigar CONFIRMATIO Identity of the S Title:	REGISTRATION Name One Two PRODUCT LISTI Product Category Other	Joe Smith I (Establishment Address 7400 Fullert 22153, UNI 10903 New Spring, MD, ING Product Identification Number 12345	on Road, Spring TED STATES Hampshire Ave, 20903, UNITED Product Identification Number Type Item/Catalog Number	Silver STATES Possible Duplicate No	Active Active Estable Name Estable One; Estable	ishment (s) ishment ishment Two	
Owner Name: If the owner do any other name such names: SECTION IV - I Establishment I Establishment I Establishment I Cuban Cigar CONFIRMATIC Identity of the S Title: Position Title:	REGISTRATION Name One Two PRODUCT LIST Product Category Other ON STATEMENT Signatory: Own	Joe Smith I (Establishment Address 7400 Fullert 22153, UNIT 10903 New Spring, MD, ING Product Identification Number 12345	on Road, Spring TED STATES Hampshire Ave, 20903, UNITED Product Identification Number Type Item/Catalog Number Full Name:	Possible Duplicate No Joe Sr	Active Active Estable Name Estable One; E	ishment (s) ishment ishment Two	

Figure 48

2. View/Update Registration Information

After users have logged into the "**Tobacco Registration and Product Listing**" from FDA Industry Systems, they should navigate to the TRLM Main Menu page as shown below.

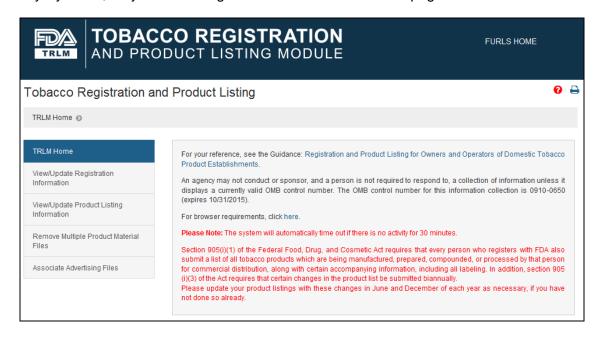


Figure 49

Once the registration is submitted the TRLM Main Menu will display the following options:

- View/Update Registration Information
- View/Update Product Listing Information
- Remove Multiple Product Material Files
- Associate Advertising Files

View/Update Registration Information

To view, add, and edit establishment information, users can select "View/Update Registration Information" from the TRLM Main Menu. The system will display the establishments that were added to users' registration, (as shown below in Figure 50).

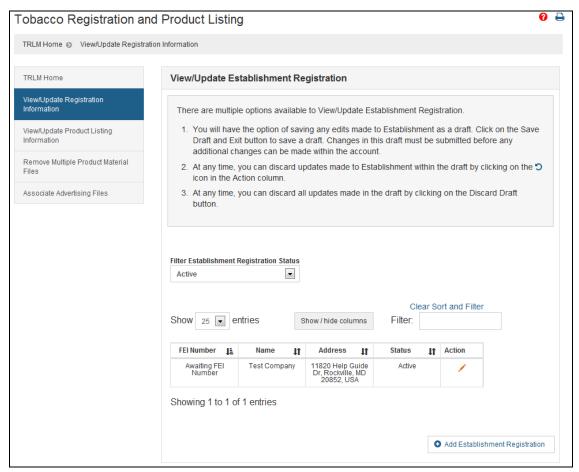


Figure 50

The Establishment Summary page contains a list of the establishment(s) that was added to users' registration. Users may add a new establishment to the registration or view / update an existing one.

To add new establishments to the registration users can select the "Add Establishment Registration" button. (For details about adding a new establishment, refer to Add Establishment Registration).

2.1 View/Update Existing Establishment Registration

To view/update an existing establishment, select the applicable icon. Users will navigate to the View/Update Establishment Registration Review page for the selected establishment as shown below. Users can view/update previously entered sections of the registration by clicking the appropriate "Edit" button.

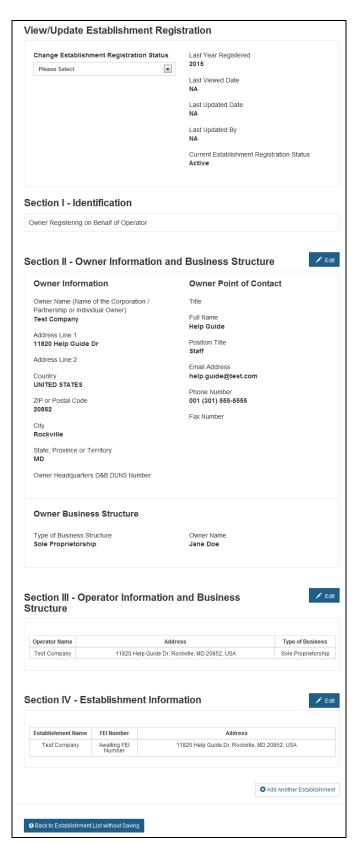


Figure 51

Establishment Registration Review

On the Establishment Registration Review page users can perform the following actions:

- Update the status of the establishment
- View or update registration information
- Complete annual registration
- View/Update Another Registration
- Add Another Establishment
- Continue to submit

Update the status of the establishment:

Users can change the establishment registration status of an active establishment to "**Inactive**" or change the establishment registration status of an inactive establishment to "**Active**."

When users change the status of an establishment, the system will prompt users to enter the date of the establishment status change as displayed below (this cannot be a future date).

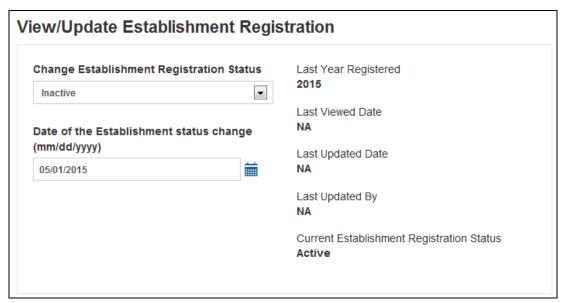


Figure 52

When continuing to submit after changing the status of an active establishment to 'Inactive,' the system shall display a warning message, as shown below, if the active Product Listing(s) associated with it are not associated with any other active establishment.

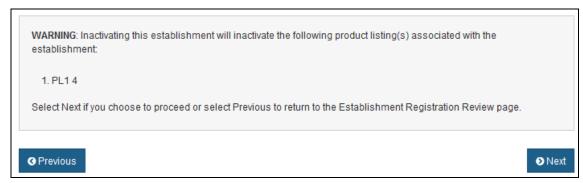


Figure 53

If the user acknowledges inactivating the associated Product Listing(s), the user selects "Next" to navigate to the Marketing Status Change Date page. Users will be prompted to provide the "Marketing Status Change Date" for each of the Product Listing(s) being inactivated as displayed below (this cannot be a future date). The user may then continue to submit the status update.

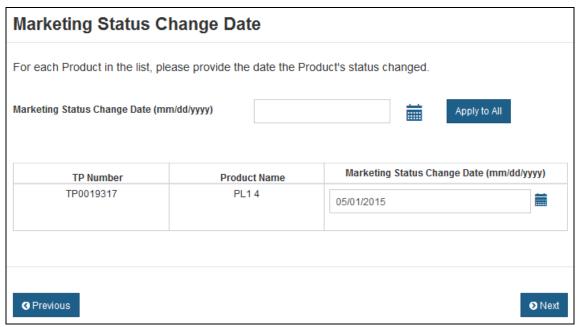


Figure 54

When continuing to submit after changing the status of an inactive establishment to "**Active**," users will be navigated to the "**Add Product Listing**" page, (as displayed below).

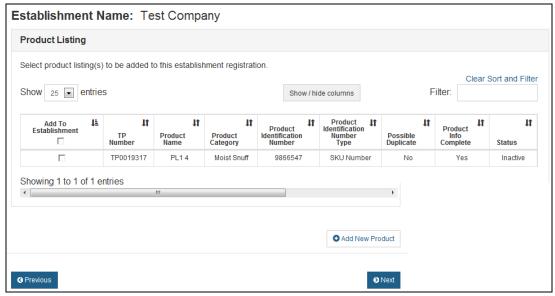


Figure 55

This page displays all the Product Listing(s) that were previously submitted. Users must select the Product Listing(s) to be associated with the establishment that is being activated. Users may select existing product(s) by checking the "Add to Establishment" checkbox alongside each Product Listing. Users may also choose to add a new product by selecting the "Add New Product" button. The user may then continue to submit the status update.

Complete Annual Registration:

In order to complete annual registration, users may update establishment information in Section IV – Registration (Establishment Information) by clicking the "Edit" button on the Establishment Registration Review page. If there are no changes, users may select the checkbox labeled "Please check this box if there are no changes to the establishment information in Section IV below," (as displayed in Figure 56).



Figure 56

View/Update Another Registration:

If there is more than one registered establishment for the account, users may view/update another establishment by selecting the "Continue to View/Update Another Registration" button on the View/Update Establishment Registration review page. This navigates users to the View/Update Registration Information main menu screen so they may select another establishment to view or update.

Add another Establishment:

Users may add another establishment by selecting the "Add another Establishment" button on the View/Update Establishment Registration review page. The system navigates to Section IV -

Registration (Establishment Information) page where users can enter information for a new establishment.

Print Submission:

Users may print the submission by selecting the "**Print Submission**" button. A new browser window will open which allows users to print the registration information that has been entered so far. When finished, users can close the separate browser window to return to the TRLM application.

Continue to Submit:

Once users have reviewed the registration, users can submit updates by selecting the "Continue to Submit" button. Users will navigate to Section VI: Confirmation Statement. See below.

Section VI – Confirmation Statement Section

This page will display the confirmation statement before successfully submitting any changes.

Note: Users must agree to the Confirmation Statement before submitting.

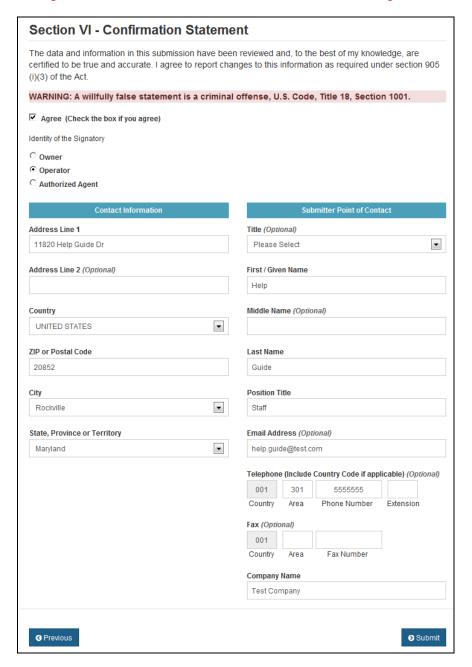


Figure 57

In this section users are required to select the Identity of the Signatory. The options are: "Owner," "Operator," or "Authorized Agent."

- If users select "Owner," the relevant contact information fields will be pre-filled with the Owner's contact information and can be edited.
- If users select "Operator," the relevant contact information fields will be pre-filled with contact information for the Operator and can be edited. When the registration has more

than one Operator, users can select the Operator from a drop-down list.

• If users select "Authorized Agent," users must enter the authorized agent's contact information.

Upon completion of this section, the registration is ready for submission. Click "**Submit**" and the system will display a message that the registration information has successfully been submitted (as shown below).

In order to receive notifications, users should configure their email's Spam or Junk folders to allow messages from CTPRegistrationandListing@fda.hhs.gov.



Figure 58

Users may print the submission by selecting the "**Print Submission**" button, or users may choose to return to the TRLM main menu by selecting the "**TRLM Home**" links on the screen.

2.2 Add Establishment Registration

To add a new establishment to a registration, select the "Add Establishment Registration" button from the View/Update Establishment Registration screen.

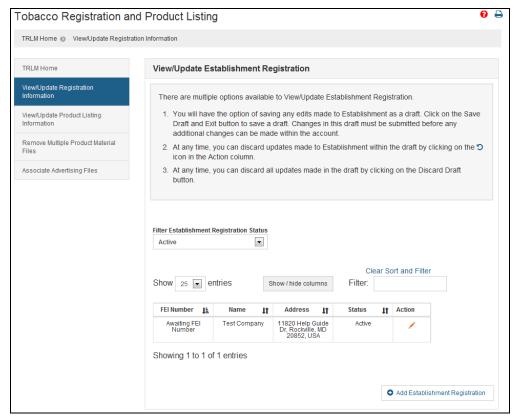


Figure 59

The system navigates to the Section IV - Registration (Establishment Information) screen as displayed in below. On this page users enter their information for a new establishment and a new establishment Point of Contact. When the registration has more than one Operator they will be required to select at least one Operator for the establishment from the "Select Operator(s) for this Establishment" multiple-select list box. If required, users may choose more than one Operator to be associated with the establishment. Users may also choose to add another Operator to be associated with the establishment by selecting the "Add another Operator" button.

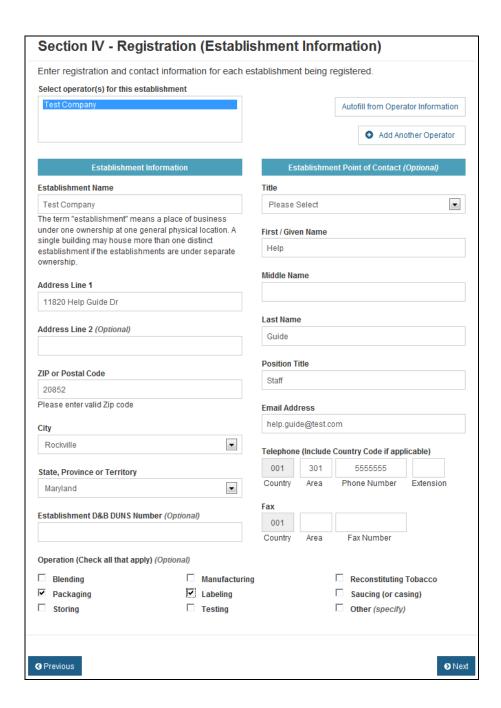


Figure 60

On this page users can enter information for the new establishment and the Point of Contact. When the registration has more than one Operator, users will be required to select at least one Operator from the "Select Operator(s) for this Establishment" select list box. If required, users may choose more than one Operator=. Users may also choose to add another Operator to be associated with the establishment by selecting the "Add another Operator" button.

NOTE: The following fields in Section IV are required:

- Establishment Name
- Address Line 1
- ZIP or Postal Code
- Citv
- State, Province, or Territory

2.3 Address Validation

The system performs an address validation as seen below. If the address is valid, no action is taken and the system continues to the next page where users can add Product Listings to the establishment as shown below.

If there are minor differences to the address entered, the system will display the validated address as shown below. If the address entered cannot be verified, the system will display a warning message as shown below. If the establishment name and address is found to be a possible duplicate, the system will display a warning message as shown below.

Users can make changes to the address provided by selecting the "Edit Address" option, or select the "Accept Validated Address" button to proceed to add Product Listing(s) to the establishment.

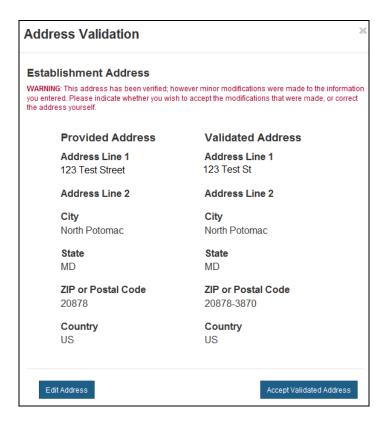


Figure 61

The system will display a warning message when the establishment name and address entered is found to be a possible duplicate. Users can make changes to the establishment by selecting the "Back to Establishment Information" option. If users verify that the establishment name and address is not a duplicate, users can continue to add Product Listing(s) to the establishment.



Figure 62

2.4 Add Product Listings to Establishment

Upon completing the establishment information users will navigate to the "Add Product Listing to Establishment" page, (as displayed below).

This page displays all the Product Listings that have been added to the registration. Users may select existing products by selecting the "Add to Establishment" check box for the appropriate product or by adding a new product by selecting the "Add New Product" button.

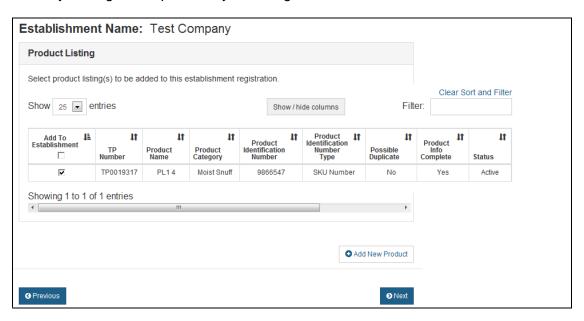


Figure 63

2.5 Add New Product

Selecting the "Add New Product" button will navigate users to the Section V: Product Listing page, as displayed below. Users can enter the required information for the new product added.

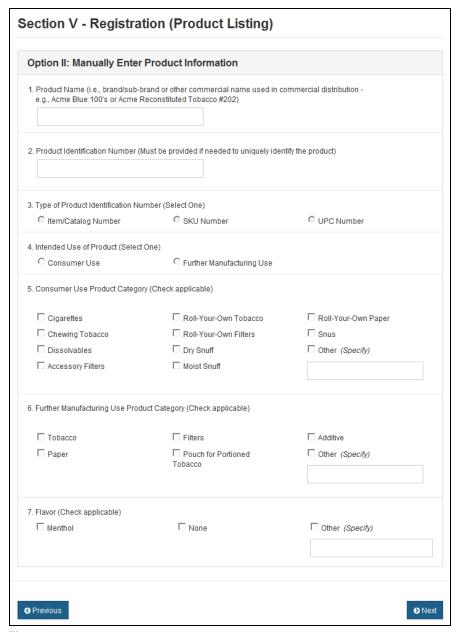


Figure 64

Users should <u>complete</u> the "**Advertising, Labeling, and Consumer Information**" sections for the Product Listing added. After adding products to establishments users can click "**Next**" to navigate to the "**Registration Review**" page.

Registration Review Page

The system displays the registration review page and all entered information for review, as shown in below.

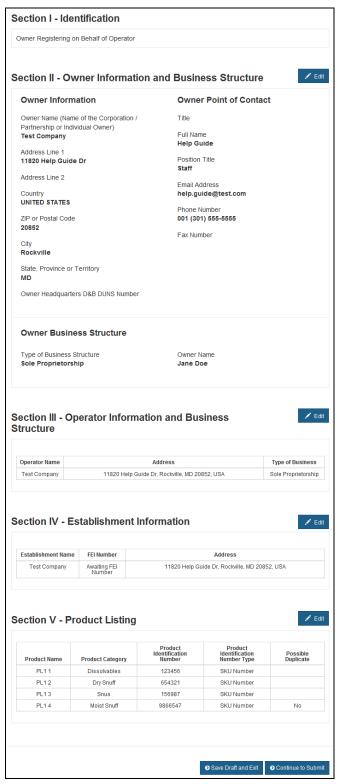


Figure 65

After reviewing or updating the registration information, users can edit information for each section, save draft and exit, or users can submit the update(s).

 Users may edit information from each section of the registration by selecting "Edit" for the section to be edited.

- Users can "Save Draft and Exit" the registration or product listing. Changes in the draft must be submitted before any additional changes can be made with the account
- Users may choose to submit by selecting the "Continue to Submit" button. Users can navigate to Section VI: Confirmation Statement.

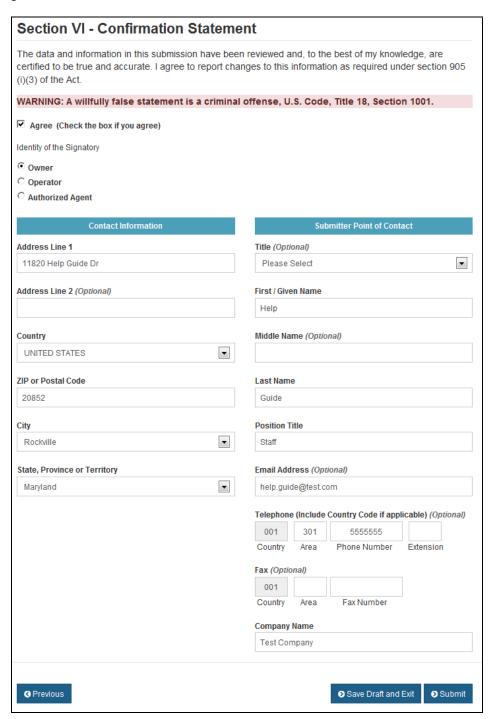


Figure 66

Click "**Submit**" to submit the registration information. The system displays a message that the registration and Product Listing information has successfully been submitted as shown below.

Submission Confirmation

Thank you for submitting your registration and product listing. You will receive an acknowledgement from the Center for Tobacco Products when your submission has been processed. In order to receive notifications, please configure your email spam/junk to allow messages from CTPRegistrationandListing@fda.hhs.gov.



Figure 67

3. View/Update Product Listing Information

3.1 View/Update Product Listing Information

To view, add and update Product Listings for a registered establishment, select the "View/Update Product Listing Information" option from the TRLM Main Menu. A list of the Product Listings that were added to the registration is displayed.

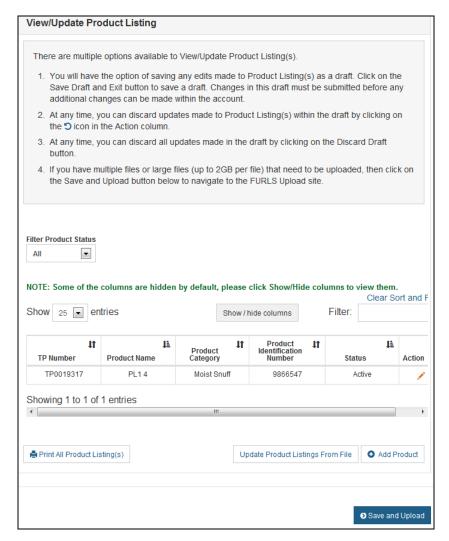


Figure 68

3.2 View/Update Selected Product

To view/update an existing product, select the icon associated to the desired product. The review page for the selected product is displayed.

View/Update F	Product Listin	ng			
Change Marketing	g Status		Last \	/iewed Date	
Please Select	-	•	NA		
			Last (Ipdated Date /2015	
				Jpdated By Guide	
				nt Marketing Status e - Reintroduced to Ma	rket
			7.0		
Product Inforn	nation				🖍 Edit
TP Number TP0019317					
Product Name					
Product Identification	n Number				
Type of Product Ide	ntification Number				
Intended Use of Pro	oduct				
Consumer Use Proc	duct Category				
Flavor					
None					
Advertising					🖍 Edit
Type of Advertising Material	Title	Unique ID Internal ID N) or umber	Date First Disseminated	Uploaded File
Magazine Ad	Help Guide Advertising	5555		05/01/2015	Testxlsx
Labeling					🖍 Edit
Type of Labeling Material	Title	Unique ID o	or mber	Date First Disseminated	Uploaded File
Package Label	Help Guide Label	6543221	IIDCI	05/01/2015	Testxisx
Consumer Info	ormation				∕ Edit
Type of Consumer Material	Title	Unique ID o Internal ID Nu	or mber	Date First Disseminated	Uploaded File
Consumer Brochure	Help Guide Brochure	12345		05/01/2015	Test.xlsx
Establishment	:				✓ Edit
Associated	Establishment Name			Addres	
▽	Test Company	Awaiting Numb	er	11820 Help Guide Dr, Rock	
V	Test Company	Awaiting Numb	FEI er	11820 Help Guide Dr, Rock	ville, MD 20852, USA
				② View/Update/Add A	nother Product Listing
◆ Back to Product List w	ithout Saving				

Figure 69

From the Product Listing Review page users can update the product's marketing status.

Users also can view and update the product's information, and advertising, labeling, or consumer information by clicking the appropriate "**Edit**" button. The system will display the previously

submitted entries for the selected section. When users finish updating the section, they can click "**Next**" to return to the Product Listing Review page.

If users registered more than one establishment, they can view and update the establishments associated with the product.

After updating the product, users can view, update, and Add another Product Listing, or users can submit the update(s). The system will display the Product Listings Summary page.

When users choose to "Continue to Submit," the system will display the Confirmation Statement.

Users can change the marketing status of an active Product Listing to "**Discontinued**" or change the marketing status of an inactive Product Listing to "**Reintroduced to Market**." The system will prompt users for the date that the marketing status changed.

ew/Update Product Listing			
Change Marketing Status	Last Viewed Date		
Discontinued	NA		
Marketing Status Change Date (mm/dd/mm/)	Last Updated Date		
Marketing Status Change Date (mm/dd/yyyy)	07/20/2015		
<u> </u>	Last Updated By		
	Help Guide		
	Current Marketing Status Active - Reintroduced to Marke		

Figure 70

When a Product Listing is reintroduced to market and if users registered more than one establishment, they will select establishment(s) to be associated with the product from the Establishment section on the Review page.

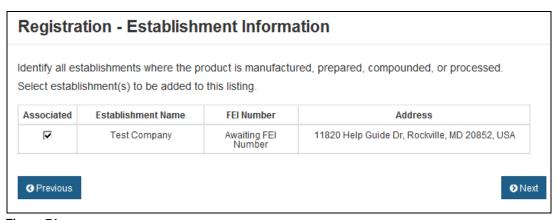


Figure 71

Users must select at least one establishment from the list to associate with the Product Listing. Click "**Next**" to return to the Product Listing Review page then click "**Continue to Submit**" to display the Confirmation Statement.

Note: Users must agree to the Confirmation Statement before submitting.

Section VI - Confirmation Statem	ent
The data and information in this submission have be certified to be true and accurate. I agree to report ch (i)(3) of the Act.	en reviewed and, to the best of my knowledge, are anges to this information as required under section 905
WARNING: A willfully false statement is a crimina	al offense, U.S. Code, Title 18, Section 1001.
✓ Agree (Check the box if you agree)	
Identity of the Signatory	
Owner○ Operator○ Authorized Agent	
Contact Information	Submitter Point of Contact
Address Line 1	Title (Optional)
11820 Help Guide Dr	Please Select 🔻
Address Line 2 (Optional)	First / Given Name
	Help
Country	Middle Name (Optional)
UNITED STATES	
ZIP or Postal Code	Last Name
20852	Guide
City	Position Title
Rockville	Staff
State, Province or Territory	Email Address (Optional)
Maryland	help.guide@test.com
	Telephone (Include Country Code if applicable) (Optional)
	001 301 5555555
	Country Area Phone Number Extension
	Fax (Optional)
	Country Area Fax Number
	Company Name
	Test Company

Figure 72

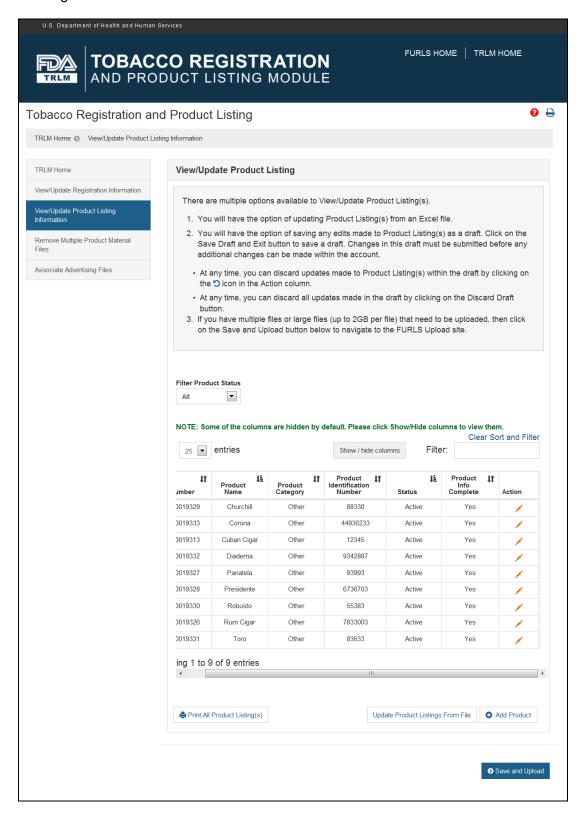
On this page users are required to select the Identity of the Signatory. The options are: "Owner", "Operator", or "Authorized Agent".

- If users select "Owner" the relevant contact information fields will be pre-filled with contact information for the Owner and can be edited.
- If users select "**Operator**" the relevant contact information fields will be pre-filled with contact information for the Operator and can be edited. When the registration has more than one Operator, users can select the Operator from the drop-down list.
- If users select "Authorized Agent" they must enter the Authorized Agent's contact information.

Upon completion of this section, the registration is ready for submission. Once users click "**Submit**" the system will display that the registration and Product Listing information has successfully been submitted. In order to receive notifications, users should configure their email's Spam or Junk folders to allow messages from CTPRegistrationandListing@fda.hhs.gov.

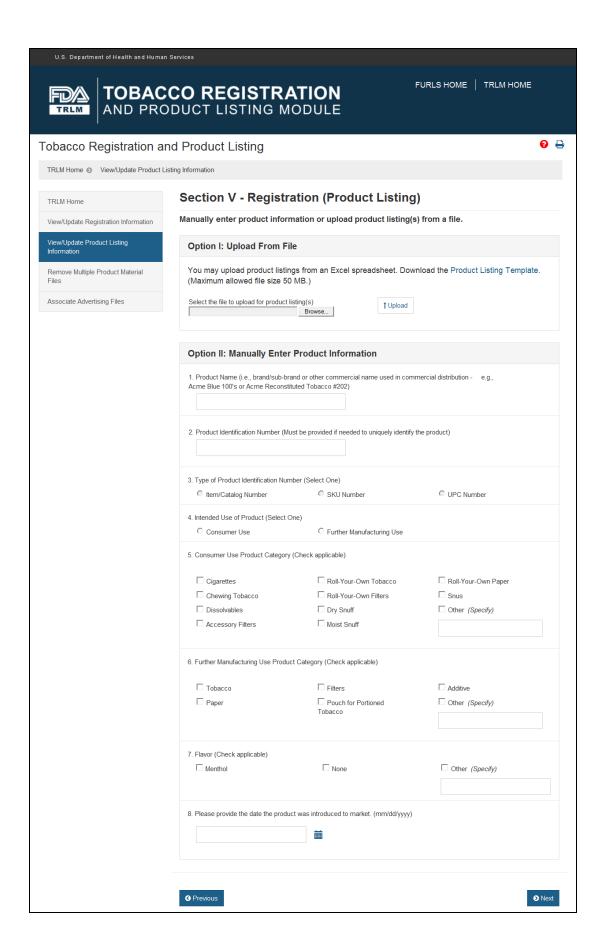
3.3 Add Product Listing

To add products for a registered establishment, users can select "View/Update Product Listing Information" from the TRLM Main Menu. The system will display the added Summary of the Product Listings.



The View / Update Product Listing page contains a list of the products that were added to the registration and provides the option to add a Product Listing.

Users can click "Add Product" to enter the new product's information.



Product Name (required)

 Brand/sub-brand or other commercial name used in commercial distribution (e.g., Acme Blue 100s). Users can enter up to 120 characters for Product Name.

Product Identification Number (optional)

 Users can enter up to 100 characters. Users must enter Product Identification Number if needed to uniquely identify the product. If users enter a Product Identification Number users also must enter "Type of Product Identification Number."

Type of Product Identification Number (required if Product Identification Number was entered)

 If users entered a "Product Identification Number", users must select a "Type of Product Identification Number."

Intended Use of Product (required)

Users must select either "Consumer Use" or "Further Manufacturing Use."

Consumer Use Product Category (required if Consumer Use was selected for Intended Use of Product)

 Users must select one or more "Product Category." If the appropriate Product Category is not listed, users must select "Other" and enter its category in the text field.

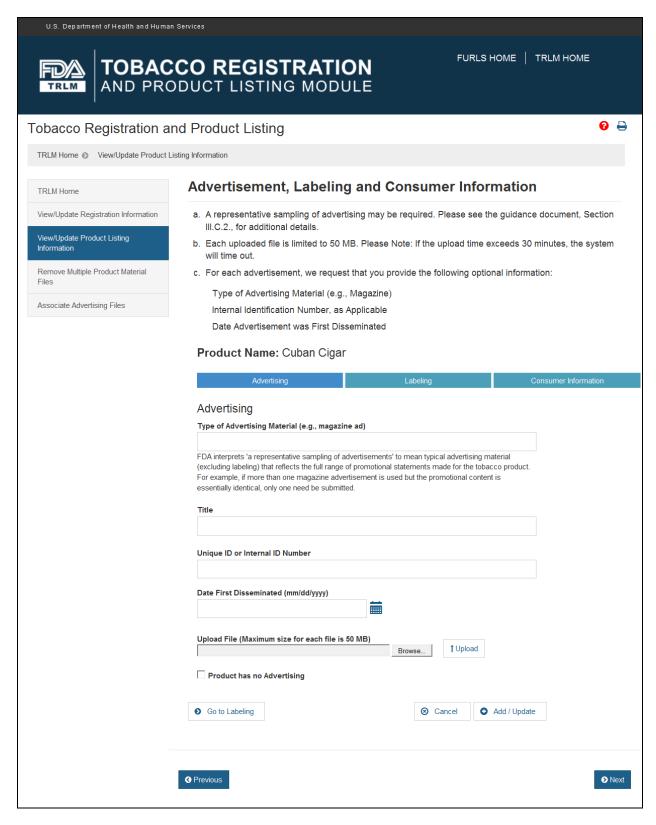
• Further Manufacturing Use Product Category (required if Further Manufacturing was selected for Intended Use of Product)

 Users must select one or more uses. If the appropriate Product Category is not listed users must select "Other" and enter its category in the text field.

Flavor (optional)

 Users can select one or more flavors. If the product's Flavor is not listed, users can select "Other" and enter a flavor in the text field.

When users choose to continue from the Product Information page, the system will display the Advertising, Labeling, and Consumer Information page.



A representative sampling of advertising for the product may be required. Users should refer to the Section III.C.2 Guidance document for additional details.

Users can enter information about the product's advertising on the Advertising Information page. Users can <u>upload</u> advertising or indicate that the product has no advertising by checking the "**Product has no Advertising**" box. If users upload advertising file(s) for the product, they also have the option to enter details about the product's advertising, including:

Type of Advertising (optional)

o Users can enter up to 120 characters.

Title (optional)

Users can enter up to 120 characters.

• Unique ID or Internal ID Number (optional)

Users can enter up to 40 characters.

Date First Disseminated (optional)

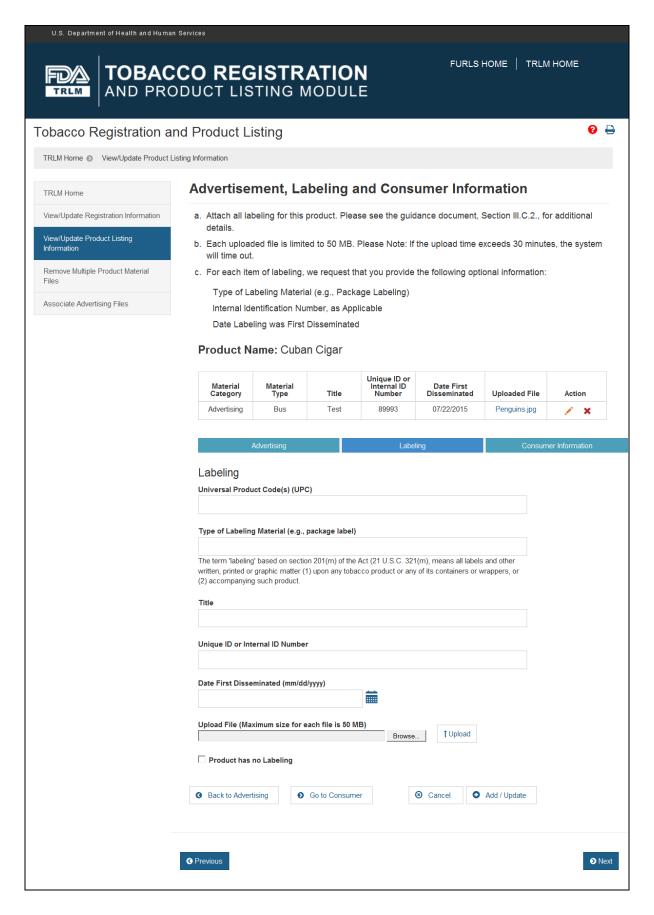
Users can select a date from the calendar icon or enter a date.

When users finish entering the product's advertising, the system will display the Advertising Summary page that lists the entire product's advertising. If users indicated that the product has no advertising, the system will display the Labeling Information page.



To edit advertising, users can click on the icon to display the Advertising Information that was previously entered. Users can edit the Advertising information and click "Continue" to return to the Advertising Summary page.

To delete advertising, users can click on the X icon.

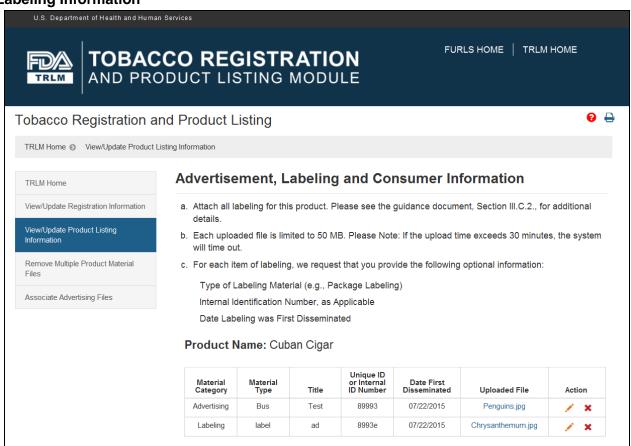


Labeling for a product is required. Users should refer to the Section III.C.2 Guidance document for additional details.

Users can enter information about the product's labeling on the Labeling Information page. Users must <u>upload</u> at least one labeling file or indicate that the product has no labeling by checking the "**Product Has No Labeling**" box for each product. If users upload labeling file(s) for the product, they also have the option to enter details about the product's labeling, including:

- Product UPC code(s) (optional)
 - Users can enter one or more UPC codes separated by commas.
- Type of Labeling Material (optional)
 - Users can enter up to 120 characters.
- Title (optional) Users can enter up to 120 characters.
- Unique ID or Internal ID Number (optional)
 - Users can enter up to 40 characters.
- Date First Disseminated (optional)
 - Users can select a date from the calendar icon or enter a date.

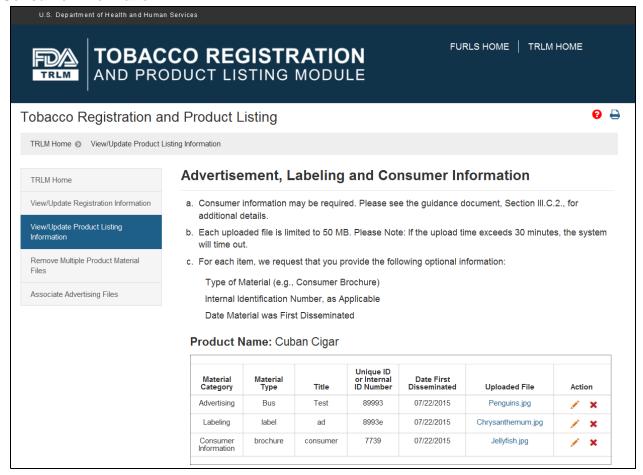
Labeling Information



To edit labeling, users can click on the sicon to display the Labeling Information that was previously entered. Users can edit the labeling information and click "Continue" to return to the Labeling Summary page.

To delete labeling users can click on the X icon.

Consumer Information

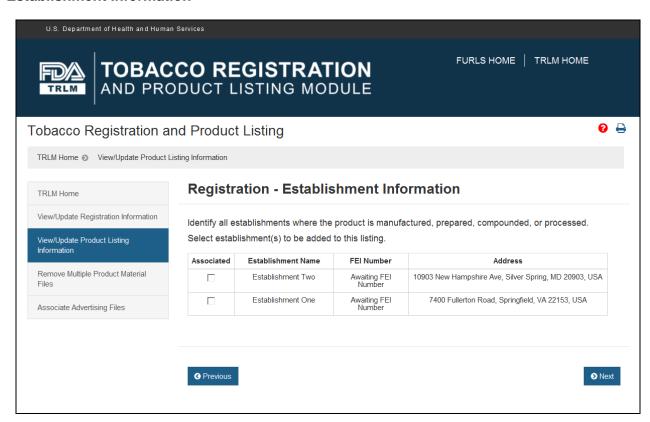


To edit Consumer information, users can click on the \(\ ^\ \) icon to display the Consumer Information that was previously entered. Users can edit the Consumer Information and click "**Continue**" to return to the Consumer Information Summary page.

To delete Consumer Information, users can click on the x icon.

If users' registration has more than one establishment. When select "**Next**" the system will display a list of the establishments added to the registration.

Establishment Information

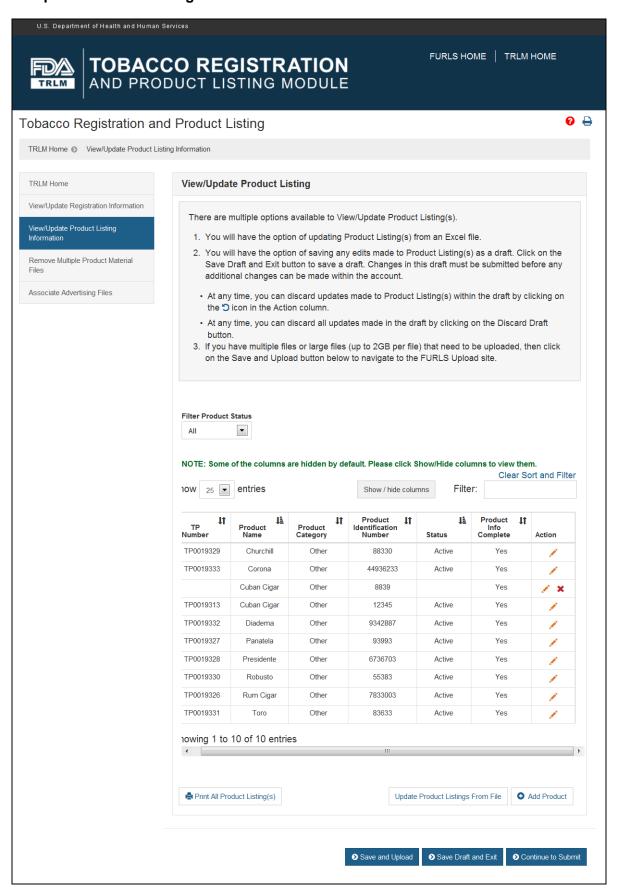


Users must select at least one establishment from the list to associate with the Product Listing's added users.

When users continue from the Establishment Information page, the system will display the Product Listing page.

From the Product Listing page users can choose to edit a Product Listing, add another Product Listing, or continue to submit.

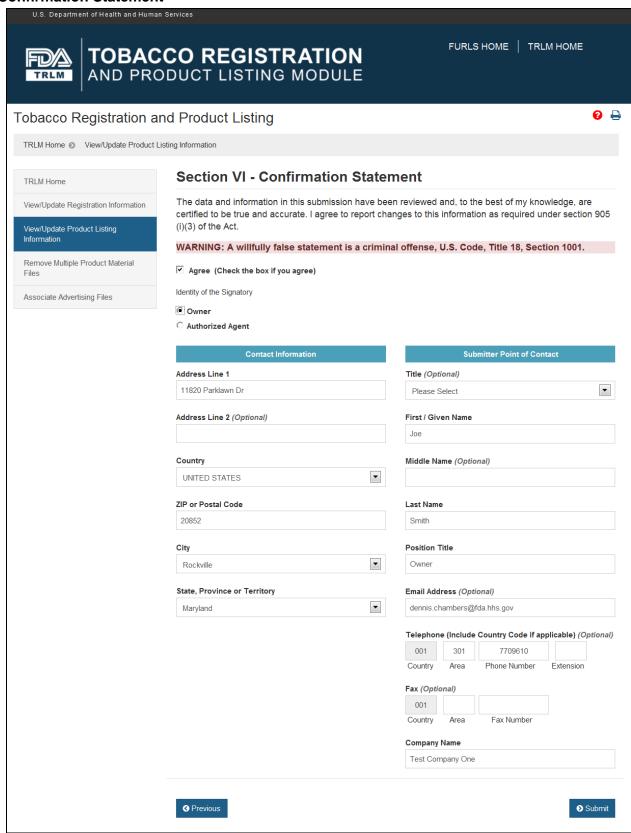
View / Update Product Listing



Users can click "Continue to Submit." The system will display the Confirmation Statement page.

Note: Users must agree to the Confirmation Statement before submitting.

Confirmation Statement



On this page users are required to select the Identity of the Signatory. The options are: "Owner", Operator", or "Authorized Agent."

• If users select "Owner," the relevant contact information fields will be pre-filled with contact information for the Owner from Section IIA and can be edited.

- If users select "Operator," the relevant contact information fields will be pre-filled with contact information for the Operator from Section IIIA and can be edited. When the registration has more than one Operator, users can select the Operator from the drop-down list.
- If users select "Authorized Agent," they must enter the authorized agent's contact information.

Upon completion of this section, the registration is ready for submission. Users can click on the "**Submit**" button. The system will display a message that users' registration and Product Listing information has successfully been submitted. In order to receive notifications, users should configure their email's Spam or Junk folders to allow messages from <a href="https://creativecommons.org/linearized-new-monses-upon continuous configure-monses-upon configur

3.4 Upload Files

To upload a file, users can click "**Browse**" to find the file to upload. Users should then click "**Upload**."

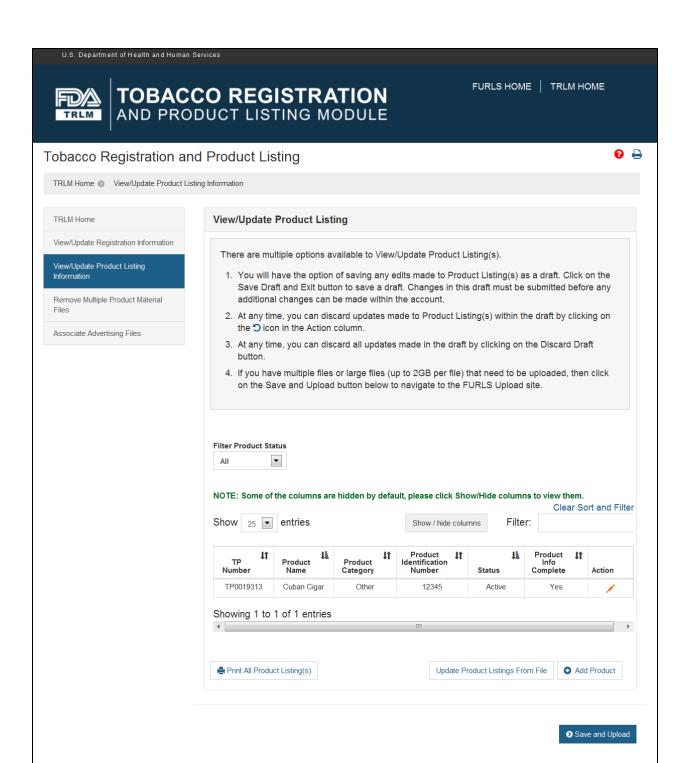
The system will display the file name and file size of the uploaded file. File size is limited to 50MB per file.

The following file types are accepted: .pdf, .xpt, .xml, .dtd, .gif, .tif, .jpg, .sgml, .mol, .xls, .xlsx, .csv, .wmv, .avi, and .zip.

3.5 Update Product Listings from File

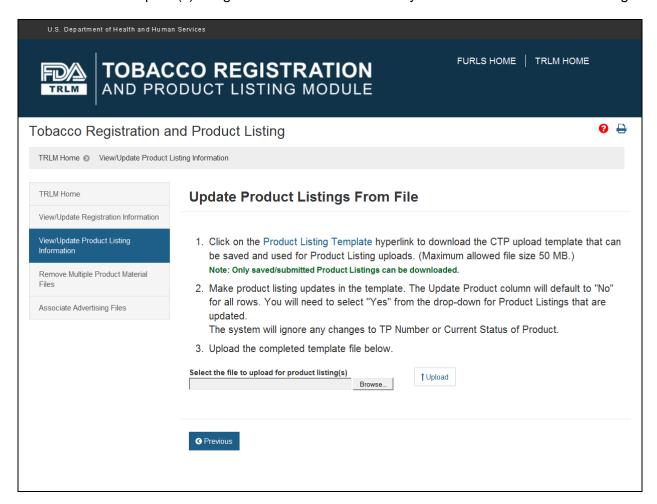
The user can update Product Listings from a file by clicking the "**Update Product Listing from File**" button and will be navigated to the page to download the Product Listing Template and the CTP upload template.

If there are multiple and/or large files, (2GB per file), that need to be uploaded, users can click on the "Save and Upload" button to navigate to the FURLS Upload site.



The user can update Product Listings from a file by clicking the "**Update Product Listing from File**" button and will be navigated to the page to download the Product Listing Template.

The downloaded template(s) will generate a Excel file with only saved/submitted Product Listings.

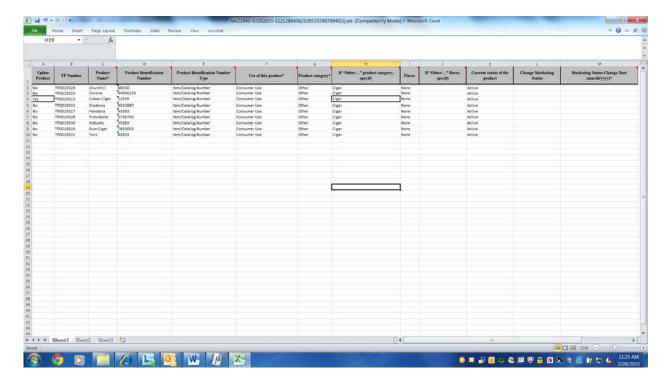


- Users should make Product Listing updates in the template(s). The "Update Product" column will default to "No" for all rows. Users will need to select "Yes" from the drop-down for Product Listings that are updated. The system will ignore any changes to TP Number or Current Status of Product.
- Product Name (required) Brand/sub-brand or other commercial name used in commercial distribution (e.g., Acme Blue 100s). Users can enter up to 120 characters for Product Name.
- Product Identification Number (optional) Users can enter up to 100 characters. Users
 must enter Product Identification Number if needed to uniquely identify the product. If
 users enter a Product Identification Number users also must enter Type of Product
 Identification Number.
- Type of Product Identification Number (required if Product Identification Number was entered) – If users entered a Product Identification Number, users must select a Type of Product Identification Number.
- Intended Use of Product (required) Users must select either Consumer Use or Further Manufacturing Use.
- Consumer Use Product Category (required if Consumer Use was selected for Intended
 Use of Product) Users must select one or more Product Category. If the appropriate

Product Category is not listed, users must select "Other" and enter its category in the text field.

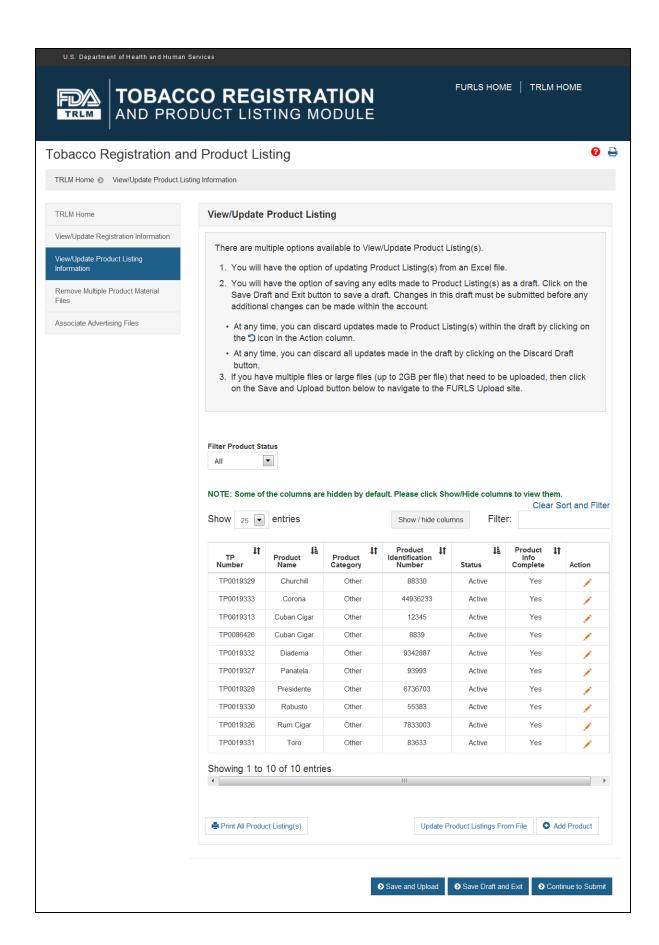
- Further Manufacturing Use Product Category (required if Further Manufacturing was selected for Intended Use of Product) – Users must select one or more uses. If the appropriate Product Category is not listed, users must select "Other", and enter its category in the text field.
- Flavor (optional) Users can select one or more flavors. If the product's flavor is not listed, users can select "Other" and enter a flavor in the text field.
- "Other" Flavor Users must select one or more uses. If the appropriate Product Category is not listed, users must select "Other", and enter its category in the text field.
- Current Status of the Product The current status of the Product (Active, Inactive, etc.).
- Change Marketing Status Change that marketing status of the associated Product.
- Marketing Status Change Date (mm/dd/yyyy) The date that the Product's marketing status was changed.

Product Updates



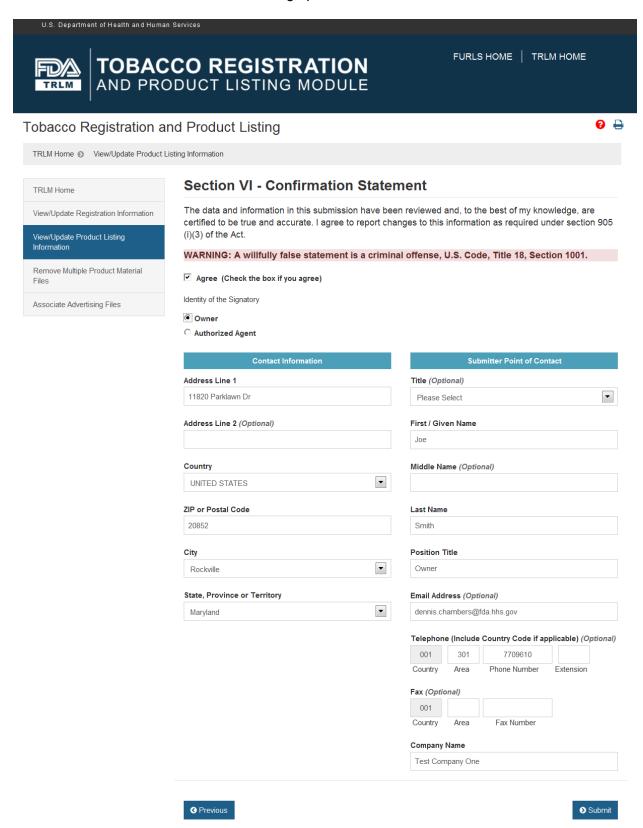
Updates

The system will display the View / Update Product Listing page; it is here that users have the option of continuing to edit the Product Listing.



Confirmation Statement

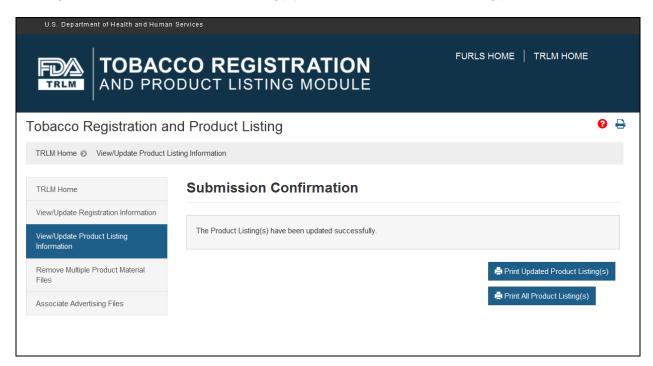
When the user selects the "Continue to Submit" button they will be navigated to the Confirmation Statement for agreement prior to submitting the Product Listing updates. Users should select "Submit" to continue with the Product Listing updates.



Submission Confirmation

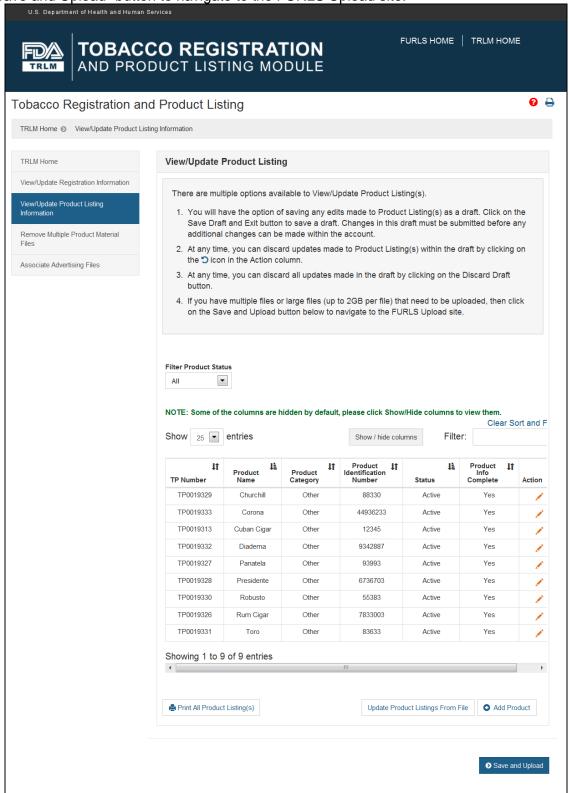
The Submission Confirmation page will display a message the Product Listing(s) have been updated successfully.

The user will have the option to print the updated Product Listing(s) from this submission by selecting "Print Updated Product Listing(s)" or "Print All Product Listing(s)."



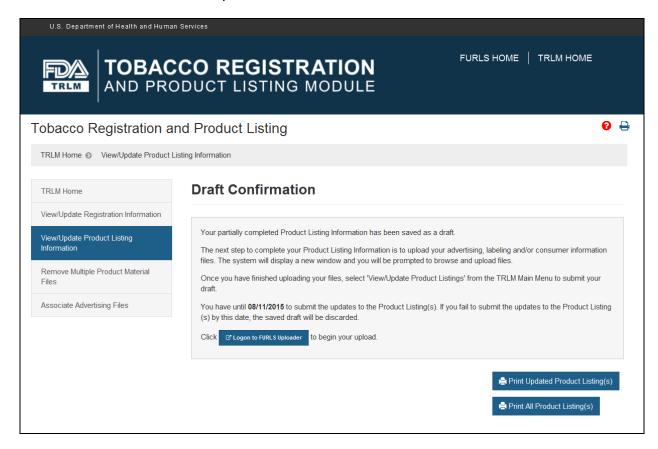
3.6 Save and Upload

If a user has multiple files or large files, up to 2GB per file, that need to be uploaded then click on the "Save and Upload" button to navigate to the FURLS Upload site.



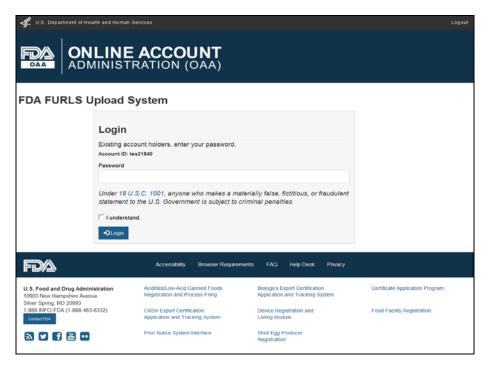
Draft Confirmation

When you select the "Save and Upload" the system will save a draft of the current registration or product listing and present the Draft Confirmation message below. The draft will provide a date when the user must submit the updates before the draft will be discarded.



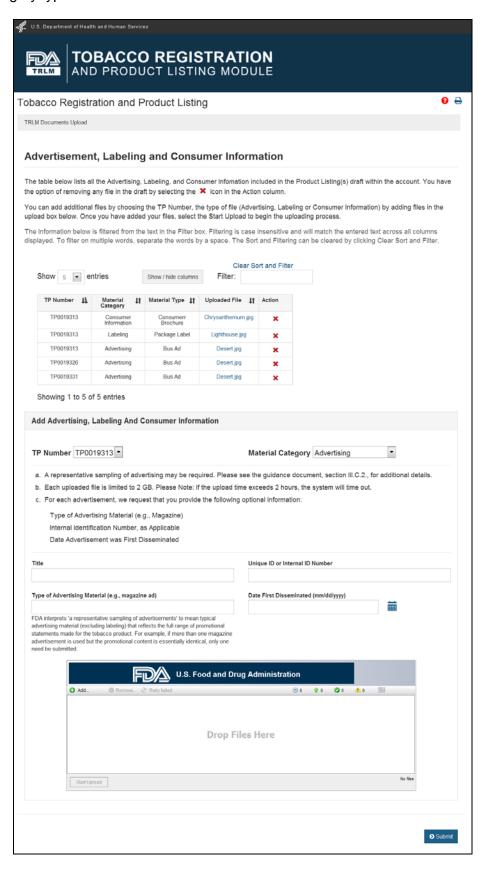
FDA FURLS Upload System - Login

You will need to login into the FDA FURLS Upload system by entering your password and checking "I understand"



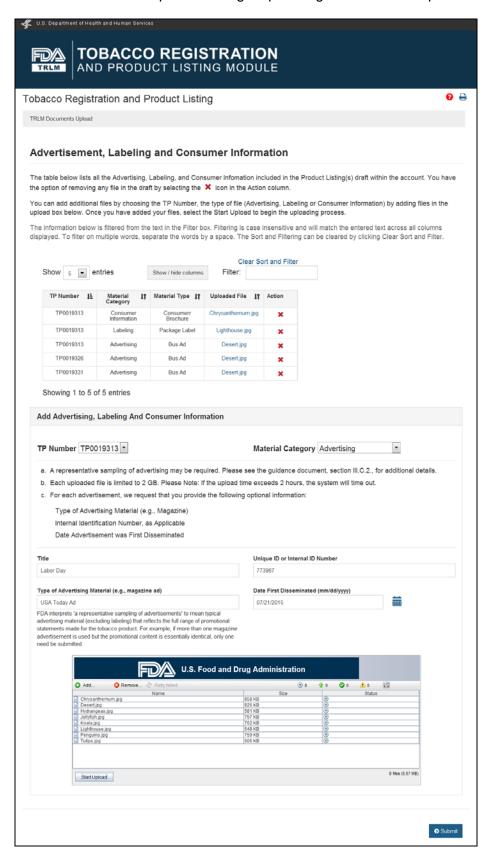
Add Advertising, Labeling and Consumer Informtion – Large File Upload

In the TP Number dropdown select the TP number that the files will be uploaded to and select the Material Category to me uploaded, Advertising, Labeling or Consumer Information. You can only load one category type at a time.



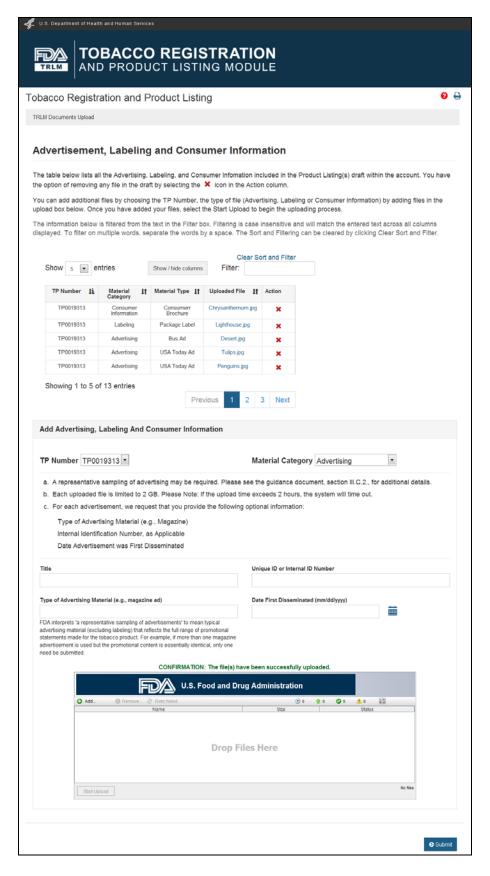
Add Upload Files

Select the "Add" button to open your browser to select the files you want to add. After the files have been added select the "Start Upload" to begin uploading the files for the product.



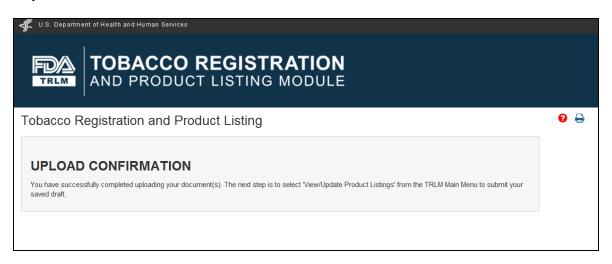
Upload Confirmation

When the files have been successfully uploaded they will be listed in a table that can be viewed. Any file can be deleted by clicking on the **X** in the Action column. After all your files have been uploaded select the "Submit" button to confirm the upload.



Upload Confirmation

The following Upload Confirmation page will display letting the user know the documents have been uploaded successfully. Select View/Update Product Listing from the TRLM main menu to submit your draft.

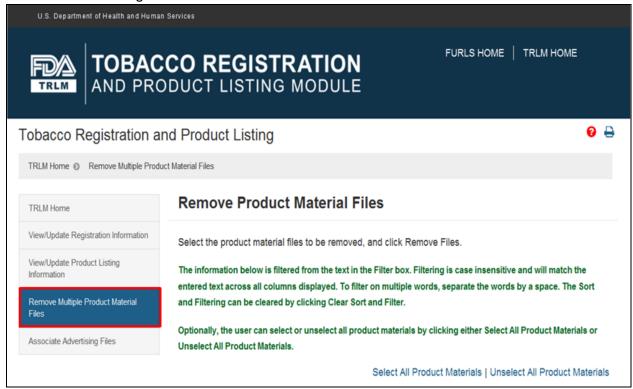


4. Remove Multiple Product Material Files

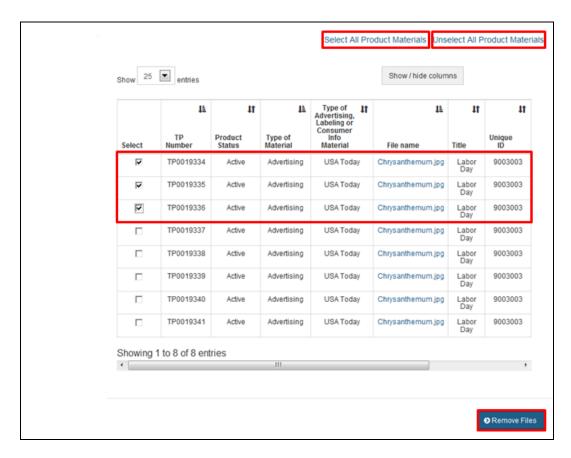
4.1 Remove Multiple Product Material Files

To remove multiple product material files for registered establishments, users should proceed with the following steps:

Users can then select "Remove Multiple Product Material Files" from the TRLM Main Menu. The system will display a list of the Product Material Files that have been added to the Product Listing.



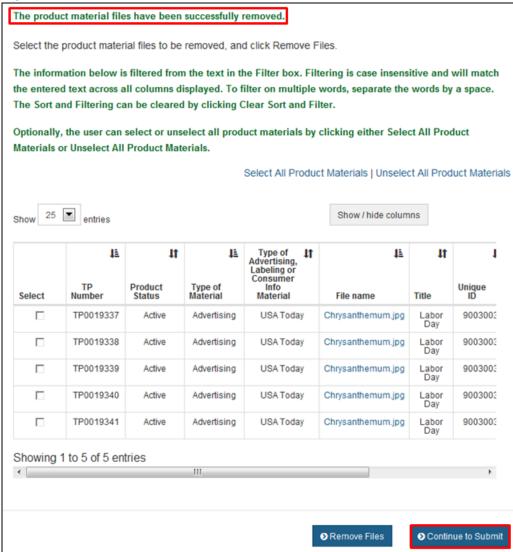
Users should then select the product material files to be removed and click "Remove Files."



Users can also select or unselect all product materials by clicking either "Select All Product Materials" or "Unselect All Product Materials."

4.2 Submit File Removal

Once the product material files have been successfully removed, a confirmation message will appear at the top of the screen.



Users can then click the "Continue to Submit" button.

4.3 Section VI- Confirmation Statement

Upon submittal, users will be directed to the Confirmation Statement, at which point they will be asked to verify the data and information of their submissions have been reviewed and are accurate.

Note: Users must agree to the Confirmation Statement before submitting.

		n reviewed and, to the best of my knowledge, are nges to this information as required under section 905(i)
WARNING: A willfully false statement is	a criminal o	ffense, U.S. Code, Title 18, Section 1001.
Agree (Check the box if you agree)		
Identity of the Signatory		
O _{Owner}		
C Authorized Agent		
Contact Information		Submitter Point of Contact
Address Line 1		Title (Optional)
		Please Select ▼
Address Line 2 (Optional)		First / Given Name
Country		Middle Name (Optional)
UNITED STATES	lacksquare	
ZIP or Postal Code		Last Name
City		Position Title
Please Select	\blacksquare	
State, Province or Territory		Email Address (Optional)
Please Select	\blacksquare	
		Telephone (Include Country Code if applicable) (Optional)
		001
		Country Area Phone Number Extension
		Fax (Optional)
		001
		Country Area Fax Number
		Company Name

Users can select the box next to "**Agree**" in order to consent to the verification of accurate data, terms of agreement, and compliance with Section 905(i) (3) of the of the Federal Food, Drug, and Cosmetic Act.

Under "Identity of the Signatory", users should signify if they are an Owner or an Authorized Agent.

Users should then enter their own Contact Information and that of the Submitter's or the authorized agent's Point of Contact information.

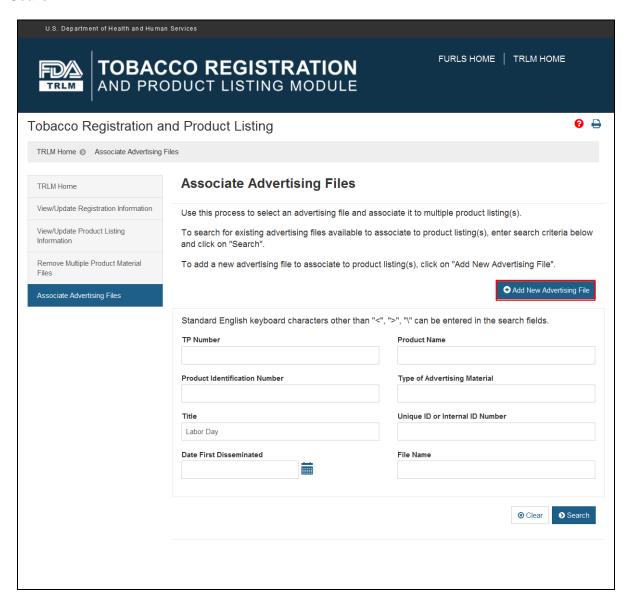
Upon completion, click "Submit." A confirmation message will appear.

5. Associate Advertising Files

Use this process to select an advertising file and associate it to multiple product listing(s).

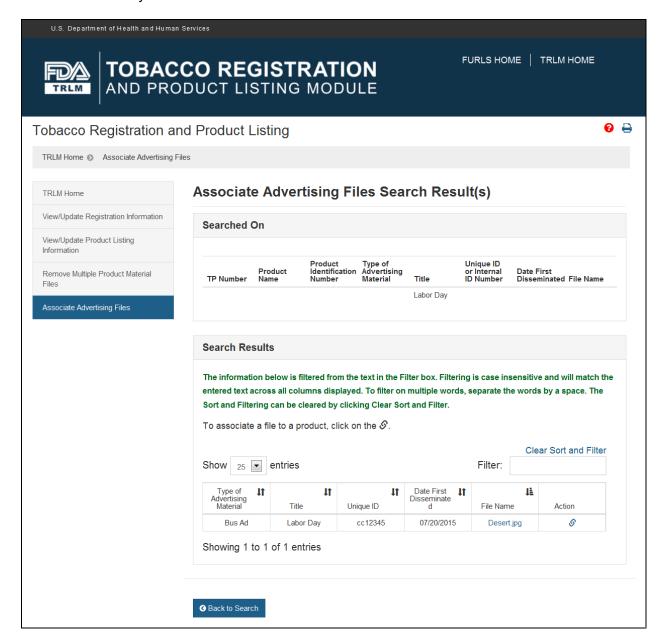
5.1 Search Existing Advertising Files

To search for existing advertising files, users can enter their desired search criteria and click "Search."



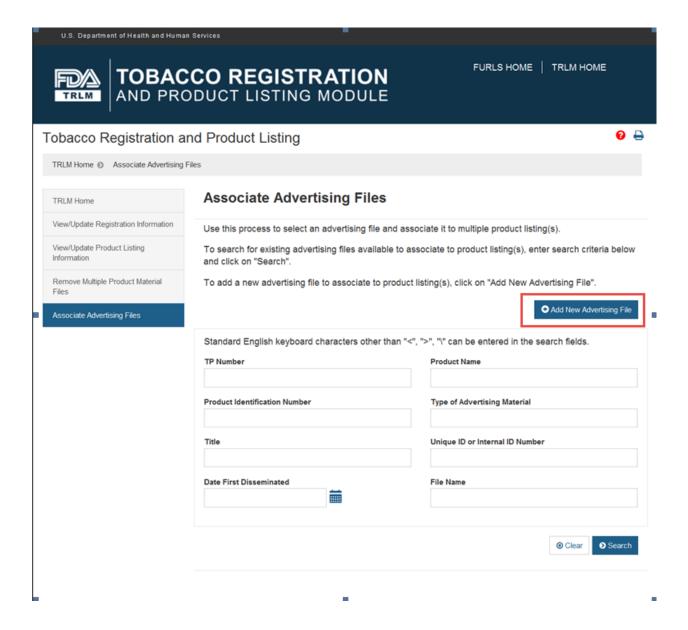
Associate Advertising Files Search Result(s)

Users will then be directed to the Search Results page. In order to associate a file to a product, click on the symbol under the "Action" column.



5.2 Add New Advertising File

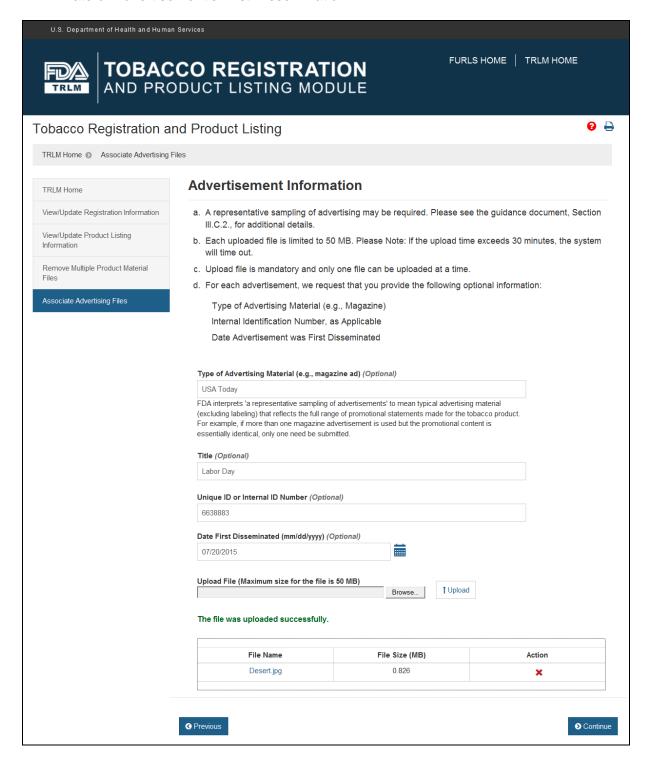
To add a new Advertising file, users can click "Add New Advertising File."



5.3 Associate File Upload

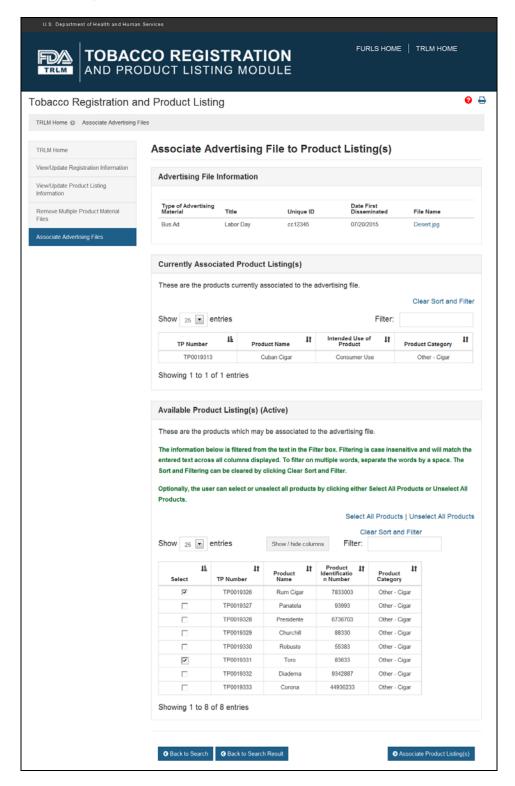
To upload a file for an advertisment, users should provide the following information where requested on the form and click "Continue."

- Type of Advertising Material
- Unique ID or Internal Identification Number
- Date of Advertisement's First Dissemination



Available Active Product Listings

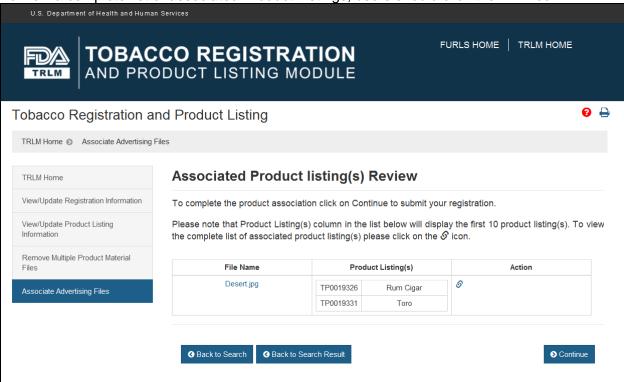
Users will be directed to "Associate Advertising File to Product Listing(s)" page. This page will contain Advertising file information, as well as associated and available Product Listings. Users can select the files they wish to search and/or filter. Optionally, the user can select or unselect all products by click "Select All Products" or "Unselect All Products."



Associated Product Listing(s) Review

To complete the product association, users should click "Continue."

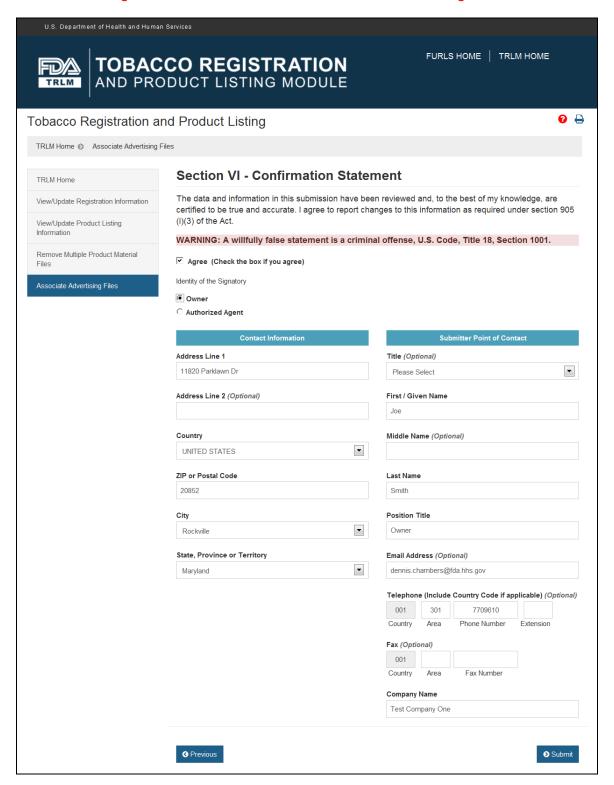
To view a complete list of associated Product Listings, users should click the é icon.



5.4 Section VI – Confirmation Statement

Users will then be directed to the Confirmation Statement, at which point they will be asked to verify the data and information of their submissions have been reviewed and are accurate.

Note: Users must agree to the Confirmation Statement before submitting.



5.5 Submission Confirmation – Associate Advertising

Once the Associate Advertising files have been submitted, users will be directed to the Submission Confirmation page. A message will display informing the user that the files have been successfully associated.

